REGION I, EPA-NEW ENGLAND DATA VALIDATION FUNCTIONAL GUIDELINES FOR EVALUATING ENVIRONMENTAL ANALYSES

U.S. EPA-NEW ENGLAND
Region I
Quality Assurance Unit Staff
Office of Environmental Measurement and Evaluation

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Preface

The Region I, EPA-New England Data Validation Functional Guidelines for Evaluating Environmental Analyses, consists of Part I, the "Data Validation Manual: The Data Quality System", December 1996 Revision, Part II, "Volatile/Semivolatile Data Validation Functional Guidelines", December 1996, and Parts III, "Pesticide/PCB Data Validation Functional Guidelines" and IV, "Inorganic Data Validation Functional Guidelines", which are not yet released. This Preface will be updated with the finalization of Part II, the release of Parts III and IV and any subsequent revisions or additions, and will accompany those revised documents.

This document was written by the QA Unit Staff of Region I, EPA New-England to formalize technical direction given since the original Region I Functional Guidelines were implemented in 1988. Data validation is necessary to ensure that only data of known and documented quality are used in making environmental decisions. As such, this guidance serves as a standard operating procedure that documents Region I's commitment to using only scientifically defensible data in environmental decision-making, it documents compliance with Headquarters' directives and guidance, and it ensures that data generated by or for the region are evaluated consistently. Part I, the "Data Validation Manual: The Data Quality System" includes by attachment other Regional and National Quality Assurance guidance documents utilized in conjunction with this new guidance to support Region I's data quality system.

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This document is under development. In the interim, validators must use the information in Part I, the "Data Validation Manual: The Data Quality System" for the data validation process and deliverables but use procedures contained in "Region I Laboratory Data Validation Functional Guidelines for Evaluating Inorganic Analyses", 6/13/88, modified 2/89, to validate inorganic data generated by or submitted to EPA-NE.

PART I - DATA VALIDATION MANUAL: THE DATA QUALITY SYSTEM

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PART I - DATA VALIDATION MANUAL: THE DATA QUALITY SYSTEM

DATA VALIDATION MANUAL: THE DATA QUALITY SYSTEM

1.0 INTRODUCTION

The Region I, EPA-New England Data Validation Functional Guidelines for Evaluating Environmental Analyses, consists of Part I, the "Data Validation Manual: The Data Quality System", and Parts II, III and IV, the specific Functional Guideline procedures for validating multi-media organic and inorganic data. Additional Functional Guideline procedures will be prepared as needed.
The data validation guidance presented in this document is intended to ensure that data of known quality are provided to both Superfund and non-Superfund EPA-NE program personnel. It is applicable to data generated for all Superfund work performed by EPA, Potentially Responsible Parties (PRPs), other Federal Agencies, States, and for oversight activities performed by EPA-NE. In addition, it is applicable to data generated for all non-Superfund work performed by EPA, other Federal Agencies, and State, Tribal and industrial partners and voluntary monitors.

These data validation procedures are not limited to Contract Laboratory Program (CLP) data. They can be employed regardless of the mechanism used to generate the data and the program for which they were generated. They may be modified to suit any organic or inorganic sample separation procedure, including chromatographic techniques such as gas chromatography or ion chromatography, and any analytical method including performance-based methods utilizing a variety of detectors. The data validation guidelines in Part II -IV of this document are not limited to aqueous and soil/sediment matrices but may be modified to evaluate other environmental matrices including, but not limited to, oil, fly ash, biological tissue and air.

2.0 DEFINITION OF DATA VALIDATION

Data validation, the first step in assessing data quality, is a standardized review process for judging the analytical quality and usefulness of a discrete set of chemical data. Thus, data validation identifies the "analytical error" associated with a data set. Data validation can also identify some (e.g., incorrect preservation techniques), but not all of the "sampling error" associated with a data set. The sum of the "analytical error" and the "sampling error" is known as the "measurement error", as per Equation 1.

> Equation 1: Measurement Error = Sampling Error + Analytical Error

The "measurement error" is used in conjunction with "sampling

variability" (spatial variability of pollutant concentrations) to determine "total error" or "total uncertainty" associated with a data set, as per Equation 2. It should be noted that "sampling error" and "sampling variability" usually contribute a greater percentage of the "total error" associated with a sampling event than the "analytical error".

Equation 2: Total Error (uncertainty) = Measurement Error + Sampling Variability

Once the "total uncertainty" has been estimated, the end user can assess the usability of a data set in the context of previously developed project Data Quality Objectives (DQOs). For additional QA Guidance, refer to EPA Order 5360.1 and Publication 9200.2-16FS contained in Attachment A.

Data validation can be viewed as a decision making process during which established quality control criteria are applied to the data. During this process, individual sample results are either accepted, rejected or qualified. Data which meet all the validation criteria are accepted as unqualified and can be used as needed, assuming that no problems occurred during the sampling events. Data which are rejected (R) for not meeting one or more of the validation criteria cannot be used at all. Some data fall into the grey area between accepted and rejected. These data are qualified as "estimated" (J) to indicate that one or more of the validation criteria were not met. Estimated data may or may not be usable depending on the intended use of the data. In general, estimated (J) data can be used after examining the reasons for data qualification and its impact on the achievement of the project DQOs. Estimated data, however, should not be used indiscriminately.

The end product of data validation is data of known and defensible analytical quality and, therefore, data should not be assessed for usability and used in environmental decision making until after completion of the data validation process.

3.0 PURPOSE OF DATA VALIDATION

Data validation serves many purposes. As previously discussed, the primary purpose of data validation is to assess and summarize the quality and defensibility of the laboratory's analytical data for the end users: site managers, risk assessors, hydrogeologists, and lawyers. The data validation process focuses on evaluating the analytical laboratory's performance so that the "analytical error"

associated with a data set can be determined. It provides a technical judgment on the validity of the laboratory results as a first step in determining their overall usability and legal defensibility. To this end, the data validator may be required to consult with the sampler in an effort to identify field problems. For example, incorrect preservation procedures result in "sampling error" and contribute to the overall "measurement error" associated with a data set. The data validation process does not include consideration of "sampling variability"; **this is left to the end user in the final assessment of data usability.**

Second, for data generated under the Superfund Contract Laboratory Program, data validation assists the Region I Technical Project Officer (TPO) in monitoring Regional CLP laboratory performance. If a laboratory fails to produce contractually-compliant data, then payment to the laboratory may be reduced or denied by procedures initiated by the EPA Field Sampling Contractor and recommended to the National Program Office (NPO) by the CLP-TPO. The TPO can also recommend that the CLP Contracting Officer take contract action against a contractually non-compliant laboratory.

Similarly, for data generated by non-CLP laboratories, data validation assists those organizations procuring analytical services in monitoring laboratory performance. If a non-CLP laboratory fails to produce contractually-compliant data, then payment to the laboratory may be reduced or denied.

It is important to emphasize that the purpose of data validation is to identify "analytical error" and not to make final determinations about the overall usability of the data for a project. The end user of the data must specify the overall Data Quality Objectives (DQOs) for the project during the up-front scoping process. Then, during data validation, the effect of individual analytical problems on the accuracy and precision of the data is detailed for specific analytes and proper qualifiers are applied to the data. Validation is just the first step in deciding whether or not data for a particular sample can be used for a specific purpose. Ultimately, only the end user can assess usability based on the "measurement error" and "sampling variability" associated with the data package. The project chemist and/or validator, however, are generally consulted by the end user to interpret decisions made with regard to measurement error during the usability determination.

4.0 REGION I, EPA-NEW ENGLAND DATA VALIDATION FUNCTIONAL GUIDELINES FOR EVALUATING ENVIRONMENTAL ANALYSES

All Superfund data generated for and/or used by EPA-NE must be validated in accordance with the most recent revision of the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating

Environmental Analyses, and this requirement should be clearly documented in the project Quality Assurance Project Plan (QAPjP) or Sampling and Analysis Plan (SAP). Any deviation from this stated data validation policy must be documented and justified in the site QAPjP or SAP and approved by the Agency.

> **If CLP methods are used to generate site data, then the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses must be used without deviation for the data validation process.**
>
> **If non-CLP methods are used to generate site data and modified validation criteria are necessary to validate those data, then all deviations to the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses must be documented in an approved QAPjP or SAP specific to that site.**

The Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses is based on the U.S. EPA Contract Laboratory Program National Functional Guidelines for Organic Data Review, February 1994 and the U.S. EPA Contract Laboratory Program National Functional Guidelines for Inorganic Data Review, February 1994, but has been modified to provide generic guidance for reviewing any organic data generated by gas chromatography (GC) or gas chromatography/mass spectrometry (GC/MS) and any inorganic data generated by Atomic Absorption (AA) or Inductively Coupled Plasma (ICP) spectrometry.

In some aspects, this document is equivalent to a standard operating procedure (SOP). In other, more subjective areas, only general guidance is offered due to the complexities and uniqueness of data relative to specific samples. Those areas where specific validation procedures are appropriate have definitive performance requirements established in the contract or the method. These requirements are not sample dependent; they specify performance on parameters that should be fully under a laboratory's control, such as laboratory blanks, calibration standards, performance evaluation standard materials, GC/MS mass calibration, peak shape and resolution.

Other performance requirements, such as the frequency of Quality Control (QC) actions, are dependent on the contract or the method, the number of samples, sample preparation technique, time of analysis, etc., and are not identical for every case or batch of samples. Individual case requirements and the impact of non-conformance must be addressed on a case-by-case basis; therefore, no specific guidance is provided. For example, the CLP organic contract requirement that a laboratory blank analysis be performed a minimum of once every twelve

hours of analysis time must be translated into the number of blanks required for a specific set of samples. The data validator may have to consider the impact on data quality for a sample analyzed thirteen hours after a blank, in terms of the quality of that particular sample data.

For some CLP data, a Contract Compliance Screening (CCS) automated review is performed by the CLP NPO Sample Scheduling and Coordination Contract (currently Contract Laboratory Analytical Services Support [CLASS], formerly Sample Management Office) to assess both technical and contractual deficiencies as presented by the laboratory in an electronic format. CCS is available to the validator and can be utilized to assist in data validation and in determining reduced value/data rejection recommendations (See Section 8.4 for additional information). However, for some CLP data (i.e., dioxin) and for all EPA-generated non-CLP data, a contractual screen is not performed by the CLP National Program Office. In the future, those organizations procuring analytical services may choose to implement their own contractual screening procedures. Until that time, the validator must assess both technical and contractual deficiencies in order to determine analytical quality as well as contractual non-compliance. Contractually non-compliant data, which are unusable for making site decisions and are considered "unacceptable" to the Region, should be considered for reduced payment or data rejection/non-payment to ensure that EPA does not pay for "unacceptable" data.

At times, there may be an urgent need to use data which do not meet all contract requirements and technical criteria. Use of these data does <u>not</u> constitute either a new requirement standard or full acceptance of the data. Any decision to utilize data that are contractually non-compliant is strictly to facilitate the progress of projects requiring the availability of the data. A laboratory submitting non-compliant data may be required to re-extract and/or reanalyze samples and/or resubmit data even if the previously submitted data have been utilized due to urgent program needs. Data that are not fully usable may be recommended for reduced payment if those data are contractually non-compliant. Data that are rejected due to contractual non-compliance should be returned to the laboratory and payment denied. Data that have been rejected and returned to the laboratory cannot be used by the Region in site decisions.

If the nature of the sample itself limits the attainment of contract or method quality control and/or validation specifications, appropriate allowances must be made. The overriding concern of the Agency is to obtain data which are technically valid, legally defensible, of known quality, and ultimately usable in making site decisions.

5.0 GENERAL OVERVIEW OF THE DATA VALIDATION PROCESS

In order to perform data validation, certain quality control (QC) checks and analytical procedures must be performed in association with the analysis of the environmental samples. Examination of the results of these checks and procedures allows the trained validator to determine the analytical quality of the data in question.

To provide data of known quality, the data validator should: 1) review the data package to ensure that it contains all the required documents and forms, 2) assess the results of all QC checks and procedures, and 3) examine the raw data in detail to verify the accuracy of all information presented by the laboratory. These three levels of review constitute the Region I Tiered Validation approach. Refer to Attachment B, Region I Tiered Organic and Inorganic Data Validation Guidelines, July 1, 1993, Draft or most recent revision. Note that the tiered validation procedures specific to the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses have been incorporated into the text in each section of Parts II-IV.

Data completeness is the first item checked during validation. The validator needs all the laboratory documents in order to verify the accuracy of sample analysis results reported by the laboratory and to ensure the legal defensibility of the data. Prior to submitting sample results, the laboratory must do a complete file purge. In the CLP, this is known as the Complete SDG File (CSF) purge. This purge assembles all the supporting documentation and deliverables needed to substantiate the reported results that are used in site decisions and/or litigation support. If any part of the complete file purge information is not present, then the validator or designated Regional representative contacts the laboratory to obtain the missing documentation. This process ensures that all the required deliverables are present in the package. If missing deliverables are not obtained at this time, in all likelihood they will never be recovered. Since any data package has the potential of being used in court for enforcement or to support a site decision, all CLP and non-CLP data packages must be routinely checked for completeness. Refer to Attachment C for Region I CSF Completeness Evidence Audit Program, July 3, 1991 or most recent revision. **The validator should evaluate any Performance Evaluation sample results to assess potential usability issues, as part of the first step in data validation.**

Second, the reported results of all QC checks and analytical procedures are evaluated. Items such as holding times, sample preservation techniques, QC sample results, etc., are assessed. QC samples are designed to identify problems in three specific areas: laboratory/instrument performance, sample preparation/matrix effects,

and field performance. The validator checks laboratory and instrument performance by reviewing items such as laboratory blank contamination and instrument calibration. Unusual matrix effects can be detected by examining the results from matrix spike/matrix spike duplicates (MS/MSD), surrogate spike recoveries, and internal standard responses. These matrix effects can be caused by high concentrations of non-target analytes which mask the analytes of interest. High levels of peat or clay can bind the target analytes to produce unwanted matrix effects. Potential problems originating from field sampling work are assessed by examining the field duplicate, equipment blank, and trip blank results. It should be noted that field QC checks cannot completely assess the "error" associated with field sampling procedures. If the evaluation of QC checks indicate laboratory or field problems, then the validator must discuss their impact on the data in the Data Validation Memorandum and qualify the sample results in accordance with the guidance in Parts II, III and IV of this document.

Last, the validator examines the raw data in detail to verify the accuracy of the results reported by the laboratory. Reported sample concentrations are checked by recalculating about 10% of the original calculations unless problems warrant further investigation. Proper identification of all the analytes is confirmed by examining the laboratory instrument print-outs. The validator is responsible for resolving discrepancies in the reported data with the laboratory and obtaining resubmittals from the laboratory whenever necessary. Occasionally, the identification and concentration of target analytes reported in the samples may need to be changed upon validation.

In summary, the data validation process involves the following three steps:

Tier I: The data package is checked for completeness. The DC-2 Form (Inventory Sheet) is completed and signed. This ensures that the data set is complete for potential use in court. The PE sample results are evaluated to assess potential usability issues. For Tier I validations, a Tier I Validation Cover Letter is produced by the validator.

Tier II: The results of the QC checks, analytical procedures and PE sample results are assessed and applied to the data set. This will result in the proper qualifiers being applied to the data. For Tier II validations, a Data Validation Report is produced by the validator.

Tier III: The raw data are examined in detail to check for calculation, compound identification, and/or transcription

errors. For Tier III validations, a Data Validation Report is produced by the validator.

The validation tier used to validate each data package must be documented in the first paragraph of either the Tier I Validation Cover Letter for Tier I validations, or the Data Validation Memorandum from the Data Validation Report for Tier II and Tier III validations. For Tier I validations, the Tier I Validation Cover Letter must document the site-specific justification for limiting the validation to Tier I and the validator's evaluation of the PE sample results.

In general, validation should be completed within 21 days of receipt of the data package from the laboratory. This enables the user and/or site manager to assess contractual compliance and data usability in order to make timely site decisions. Accelerated site schedules may necessitate shorter turnaround times for validation. In general, the completion of a Data Validation Report should not be delayed because the laboratory failed to forward a resubmittal. In most cases, the Data Validation Report should be completed, the laboratory omission noted, and the data qualified using professional judgment. When/If the resubmittal is received, an amendment to the original Data Validation Report should be forwarded.

In some cases, the validator must wait for critical information before the validation can be completed. In these cases, the user and/or site manager must be notified of the delay. If validation reports are time critical, the site manager may request that a partially completed Data Validation Report be generated. Subsequently, an amendment should be written to incorporate all late resubmittals.

6.0 SUMMARY OF DATA VALIDATION OBJECTIVES

Data validation must concurrently accomplish the following:

- Assess and summarize the analytical quality and defensibility of data for the end user.

- Document for the historical record all factors contributing to "analytical error" that ultimately affect data usability, such as: data discrepancies, poor laboratory practices that impact data quality, site locations for which samples were difficult to analyze, i.e., matrix effects. Also, document any "sampling error" that may be identified by the data validation process, such as, contaminated trip or equipment blanks, incorrect storage or preservation techniques, improper sampling containers, and improper sampling techniques, i.e., headspace in VOA

containers.

- Assist Regional TPOs in monitoring CLP laboratory performance for contract administration.

- Assist in monitoring any laboratory's performance of CLP methods in generating data for submittal to EPA.

- Assist in monitoring any laboratory's performance of non-CLP methods in generating data directly for EPA or for submittal to EPA.

- Identify contractually non-compliant data that are unusable by the Region. For CLP data, a letter documenting the contractual non-compliances and recommending reduced payment or data rejection must be written and addressed to the CLP-TPO, in accordance with EPA-NE Standard Operating Procedures for Submitting Data for Reduced Payment/Data Rejection, September 1991 (Attachment I). For non-CLP data generated directly for EPA, i.e., under the DAS program, contractually non-compliant data should also be identified and documented so that contractual action can be taken to ensure that the Region does not pay for unusable, contractually non-compliant data. In general, contractually non-compliant data should always be identified and documented to support any contractual action taken by the data requestor.

- Provide information concerning the effectiveness of analytical methods and SOWs, and identify problems requiring method revision and/or resolution.

7.0 ROLES AND RESPONSIBILITIES

The end users of the data are responsible at the time of project scoping for determining the validation criteria, including validation Tier, that are necessary to support the achievement of project DQOs.

The question then arises as to who is responsible for performing data validation. In general, whoever collects field samples at the site is

also responsible for validating the analytical data. An exception exists when the organization collecting the samples uses their own internal laboratory to analyze the samples; in this situation an independent third party must validate the data. In general, EPA Field Sampling Contractors working on Fund-lead sites are responsible for validating the results for samples that they collect. States working on Fund-lead sites under Cooperative Agreements with EPA are responsible for validating their own samples. Likewise, other government agencies working on Fund-lead sites under Interagency Agreements are responsible for validating results for samples that they collect from their sites, i.e., the Army Corp of Engineers. For non Fund-lead sites, PRPs and Federal Facilities traditionally have been required to use an independent third party for data validation.

When an EPA Field Sampling Contractor performs PRP or Federal Facility oversight, duplicates (splits) for approximately 10% of the PRP's or Federal Facility's samples are analyzed by EPA. The PRP or Federal Facility must validate the data for the samples which it collects. If after PRP or Federal Facility validation, the two sets of data agree within the predetermined limits presented in the EPA-approved QAPjP and/or SAP, then the EPA oversight contractor data may not need to be validated. If they do not agree within the predetermined limits, then the EPA oversight contractor data must also be validated to investigate the cause of the discrepancy. Further corrective actions may be necessary to identify the source of the discrepancy.

7.1 EPA-NE Delivery of Analytical Services (DAS) Team (Quality Assurance Unit-Office of Environmental Measurement and Evaluation)

The EPA-NE DAS Team located within the Quality Assurance Unit of the Office of Environmental Measurement and Evaluation (OEME) is responsible for developing data validation guidance, training EPA Field Sampling Contractors in data validation, and operating an oversight program to ensure that EPA Field Sampling Contractors are performing data validation in accordance with EPA-NE policy.

The DAS Team also provides technical assistance concerning analytical methods, data validation and data usability to EPA Site Managers and EPA Field Sampling Contractor Lead Chemists. Technical assistance is also offered to the States, Tribal and industrial partners, other Federal Agencies, the public, and PRPs through the responsible EPA Site Manager.

In general, OEME does not perform site-specific data validation with the exception of OEME sampling events and all dioxin/furan samples collected by EPA personnel and EPA Field Sampling Contractors.

The EPA-NE DAS Team acts as the Regional contact point for all CLP matters and maintains the EPA-NE Performance Evaluation Sample Program.

7.1.1. EPA-NE CLP-Technical Project Officer

The CLP Technical Project Officer (TPO) is responsible for monitoring the CLP contract laboratories within EPA-NE. This includes responding to the laboratory's technical questions; reviewing laboratory performance trend information and data reviews provided by the National Program Office (NPO) and other Regional TPOs; discussing and documenting CLP laboratory performance problems; tracking laboratory corrective action requests/responses; assessing the adequacy of a CLP laboratory's corrective action response; recommending contract action to the Administrative Project Officer (APO) and Contracting Officer (CO); conducting routine and problem resolution on-site audits; and monitoring the continued effectiveness of corrective actions implemented by the laboratory.

The CLP-TPO is also responsible for: reviewing and developing Superfund analytical methods and CLP SOWs; reviewing and developing CLP policies, guidance and procedures; disseminating information concerning CLP operation and available services; and participating in workgroups to revise and/or write analytical methods, National Functional Guidelines and other national QA guidance.

7.1.2. EPA-NE Data Validation Chemist

The Data Validation Chemist (DV Chemist) is responsible for all aspects of data validation within the Region, including: revising regional data validation Functional Guidelines; providing guidance in using the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses; writing reduced payment and data rejection recommendation letters to the CLP-APO; and directing the Regional Data Validation Oversight/Methods Review Program. Through the Regional Data Validation Oversight/Methods Review Program, the DV Chemist identifies analytical issues/problems and needed corrective actions in order to reduce systematic "analytical error". Sampling issues and needed corrective actions are also identified in order to reduce systematic "sampling error". This program also helps to identify inherent problems in the analytical methods that require programmatic changes.

7.1.3. EPA-NE Performance Evaluation Chemist

The Performance Evaluation Chemist (PE Chemist) is responsible for all aspects of the Performance Evaluation Program within the Region, including: preparing, stocking, distributing, and tracking PE samples; scoring EPA-provided PE sample results and providing PES Score Reports to the data validators; and trending laboratory performance on PE samples.

7.1.4 EPA-NE Regional Sample Control Center

The EPA-NE Regional Sample Control Center (RSCC) serves as the central point of contact for questions concerning Superfund sampling efforts utilizing the CLP and any future EPA-NE analytical contracts. CLP and EPA-generated non-CLP (i.e., DAS) samples are collected, preserved, packaged, and shipped in accordance with EPA-NE, DOT, and NPO policy as described in EPA-NE Standard Operating Procedures (SOPs) and guidance documents pertaining to this subject and as documented in the EPA-approved QAPjP and/or SAP. Refer to Attachments D and E for selected guidance on the subject.

The responsibilities of the EPA-NE RSCC include: scheduling CLP sample analysis slots with the NPO Sample Scheduling and Coordination Contract to correspond with the projected demand for analytical services; providing CLP sample tags, sample labels, custody seals, and CLP COC/CLP Traffic Report Forms for EPA Field Sampling Contractors; coordinating with the NPO Sample Scheduling and Coordination Contract during sampling and sample shipment, and resolving any shipment problems concerning the CLP samples; receiving CLP data from laboratories and distributing Complete SDG Files (CSFs) to Region I Field Sampling Contractors for validation; and maintaining the New England Sample Tracking System (NESTS) database which tracks information pertaining to CLP and EPA-generated non-CLP samples delivered for EPA under the DAS mechanism.

7.2 EPA-NE Site Managers

EPA Site Managers include Site Assessment Managers (SAMs), Remedial Project Managers (RPMs), On-Scene Coordinators (OSCs) and RCRA Facility Managers (RFMs). They work in the EPA-NE Office of Site Remediation and Restoration (OSRR) and have primary responsibility for directing and/or overseeing response efforts and coordinating all actions at Superfund and RCRA corrective action sites. The SAMs, RPMs, OSCs, and RFMs establish the project Data Quality Objectives (DQOs) for their sites.

EPA Site Managers coordinate scoping meetings, assembling all technical personnel and data users to help identify the appropriate analytical methods, detection levels, level of quality assurance and,

ultimately, the tier level of data validation required for specific sample results to achieve the project Data Quality Objectives. The EPA Site Managers receive copies of Data Validation Reports and Tier I Validation Cover Letters. The OEME QA Unit also receives copies of all Data Validation Reports and Tier I Validation Cover Letters for use in the Data Validation Oversight/Methods Review Program.

7.3 CLP National Program Office

The CLP is administered by the EPA National Program Office (NPO) under the Office of Emergency and Remedial Response (OERR), located in Washington, D.C. The NPO is primarily responsible for the overall management of the CLP in terms of program objectives. The NPO is also responsible for developing and administrating CLP contracts. CLP analytical contracts include Statements of Work for the organic and inorganic analyses of single-phase aqueous or soil/sediment samples. The NPO CLP short sheets and the Region I Statement of Work (SOW) short sheets for selected past and present CLP contracts are included in Attachment F.

The NPO is also responsible for formulating and implementing policy and budget; developing and administrating CLP analytical and support services contracts which include a contract responsible for sample scheduling and coordination; coordinating the production and dissemination of Superfund Performance Evaluation Samples; developing and reviewing analytical protocols; and directing CLP quality assurance in accordance with overall OERR quality assurance activities and directives.

7.3.1 NPO Sample Scheduling and Coordination Contract ([CLASS], formerly Sample Management Office)

The contractor-operated sample scheduling office provides management, operation and administrative support to the CLP under the direction of the NPO. The primary objective of this NPO contract is to maintain optimal use of program analytical resources. The contractor supports the NPO in sample scheduling and tracking and performs Contract Compliance Screening to help ensure proper and timely payment of CLP laboratories.

7.3.2 NPO Quality Assurance Technical Support Contract (QATS)

The QATS contract provides quality assurance (QA) support to the CLP under the direction of the NPO. QATS performs the following functions: preparing performance evaluation (PE) samples for CLP pre-award and post-award laboratory performance evaluations; evaluating pre-award and post-award PE sample data; performing

QA audits on CLP-generated data including mass spectrometer data tapes; and assisting in the evaluation and development of CLP analytical protocols.

7.4 Potentially Responsible Parties (Non Fund-lead)

Potentially Responsible Parties (PRPs) as defined by CERCLA, Section 107, include 1) the current owners or operators of the facility; 2) any person who at the time of disposal of any hazardous substance owned or operated the facility at which the hazardous substances were disposed of; 3) any person who by contract, agreement or otherwise arranged for disposal or treatment, or otherwise arranged with a transporter for transport for disposal or treatment, of hazardous substances; or 4) any person who accepts or accepted any hazardous substances for transport to disposal or treatment facilities or sites from which there is a release or a threatened release. "Persons" are defined by the statute as individuals, commercial entities, corporations, partnerships, associations, joint ventures and governments.

PRPs that have entered into an agreement with EPA-NE to bear the cost of site investigations and cleanup or have been unilaterally ordered to implement site cleanups when there is an imminent and substantial endangerment presented by the site, must use an independent party to validate their data. All data must be validated in accordance with the most recent revision of the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses. Any deviations and/or modifications to these Functional Guidelines must be documented in the QAPjP and/or SAP and must be approved by EPA prior to sampling.

7.5 Other Federal Agencies (Non Fund-lead)

When a Federal Agency other than EPA owns a Federal Facility designated as a Superfund site, then as mandated by Section 120 of CERCLA, that Federal Agency is designated the lead Agency for that Federal Facility Site. That Federal Agency is responsible for validating its own data in accordance with the most recent revision of the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses. Any deviations and/or modifications to these Functional Guidelines must be documented in the QAPjP and/or SAP and must be approved by EPA prior to sampling.

7.6 Other Federal Agencies (Fund-lead)

Other Federal Agencies may enter into Interagency Agreements with EPA-NE to work on Fund-lead sites. Under an Interagency Agreement, the Federal Agency, i.e., Army Corp of Engineers, may use the CLP to

analyze samples. Alternatively, it may choose to use a non-CLP laboratory to generate data for EPA. In either case, the Federal Agency should obtain a complete laboratory data package, in accordance with requirements and/or specifications described in Attachment G so that the data may be validated in accordance with the most recent revision of the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses. Any deviations and/or modifications to these Functional Guidelines must be documented in the QAPjP and/or SAP and must be approved by EPA prior to sampling.

Federal Agencies that utilize CLP for sample analysis must submit quarterly CLP sample projections to the EPA RSCC. Completed DQO Summary Forms for each sampling event must accompany the quarterly projections. To reserve sample slots, other Federal Agencies must follow the procedures outlined in Section 9.1.3.1.

All CLP Data Validation Reports should be sent to the EPA-NE RSCC who then forwards them to the EPA-NE CLP-TPO for purposes of contract administration. Non-CLP Data Validation Reports should not be sent to the EPA-NE RSCC. Rather, non-CLP Data Validation Reports (including DQO Summary Forms) and/or Final Project Reports should be forwarded to the EPA Site Manager.

7.7 States (State-lead/Fund-lead)

New England States may enter into Cooperative Agreements with EPA-NE to work on Fund-lead sites within their State. Under a Cooperative Agreement, a State may use the CLP to analyze samples. Alternatively, it may choose to use a non-CLP laboratory such as their own State laboratory to generate data for EPA. In either case, the State should obtain a complete laboratory data package in accordance with requirements and/or specifications described in Attachment G so that the data may be validated in accordance with the most recent revision of the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses. Any deviations and/or modifications to these Functional Guidelines must be documented in the QAPjP and/or SAP and must be approved by EPA prior to sampling.

States that utilize CLP for sample analysis must submit quarterly CLP sample projections to the EPA RSCC. Completed DQO Summary Forms for each sampling event must accompany the quarterly projections. To reserve sample slots, States must follow the procedures outlined in Section 9.1.3.1.

All CLP Data Validation Reports should be sent to the EPA-NE RSCC who then forwards them to the EPA-NE CLP-TPO for purposes of contract administration. Non-CLP Data Validation Reports should not be sent to the EPA-NE RSCC. Rather, non-CLP Data Validation Reports (including DQO Summary Forms) and/or Final Project Reports should be forwarded to the EPA Site Manager.

7.8 EPA Field Sampling Contractors (Fund-lead and PRP/Federal Facility Oversight)

EPA Field Sampling Contractors work under the direction of EPA Site Managers and are primarily involved in Fund-lead site work and PRP/Federal Facility oversight. Samples collected by EPA Field Sampling Contractors may be analyzed through the CLP, by the OEME laboratory or through an EPA-NE analytical contract. Alternatively, the EPA Field Sampling Contractor may be directed by EPA to procure their own analytical services.

7.8.1 EPA Field Sampling Contractor Lead Chemist

This section details the responsibilities of the EPA Field Sampling Contractor's Lead Chemist working on Fund-lead or oversight activities for EPA-NE. However, many of the activities, roles, responsibilities and qualifications discussed below are applicable to non Fund-lead work performed by a PRP or Federal Facility as well as to Fund-lead work performed by another Federal Agency (i.e., ACOE) or a State.

7.8.1.1 Project Scoping

The Lead Chemist is a key participant in project scoping meetings where project Data Quality Objectives (DQOs), plans, schedules, sampling techniques, analytical methodologies and data validation criteria including validation tiers are discussed and agreed upon by the end users of the data. The Lead Chemist should ensure that all agreed upon DQOs, plans, schedules, sampling procedures, and analytical methodologies are incorporated into an EPA-approved QAPjP and/or SAP prior to field sampling.

During the scoping meeting, the Lead Chemist must identify the CLP and non-CLP analytical methods that are needed to generate data that achieve project DQOs. If CLP methods are used, then the QAPjP and/or SAP must specify the validation tier, document that the most recent revision of the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses will be used without modification to validate the data, and must be approved by EPA-NE prior to sampling. If non-CLP methods are used and modified validation criteria are necessary to fully evaluate the data, then the QAPjP and/or SAP must document the modified validation criteria and provide justification for the modification. If modified validation criteria are not documented in the EPA-approved QAPjP and/or SAP prior to sampling, then an amendment to the QAPjP and/or SAP should be submitted and approved prior to the use of modified validation criteria.

The Lead Chemist should ensure that the appropriate data validators receive copies of the completed DQO Summary Forms. The DQO Summary Forms will identify the project DQOs, PE samples and validation tier. The Lead Chemist should also ensure that the field sampling notes for the sampling event are provided to the data validator for inclusion in the Tier I Validation Cover Letter or Data Validation Report for historical purposes.

7.8.1.2 Procuring Non-CLP Analytical Services

When required by EPA, the Lead Chemist is responsible for developing technical specifications for non-CLP analyses that may require modified validation criteria. They are also responsible for providing technical guidance to subcontracted laboratories to ensure that fully documented, technically valid, legally defensible and usable data are delivered to EPA. To this end, it is recommended that the Region I Laboratory Pre-Qualification Standard Operating Procedure from the Region I ARCS Delivery of Analytical Services Pilot Program, Final Report, Volume II. Appendices, 15 March 1994, (Attachment Q), be followed when procuring non-CLP analytical services (Attachment Q). It is also recommended that the Region I Laboratory Audit Standard Operating Procedure, from the Region I ARCS Delivery of Analytical Services Pilot Program, Final Report, Volume II. Appendices, 15 March 1994, (Attachment Q) be followed to audit laboratories performing non-CLP analyses, as well as to resolve technical problems and monitor corrective actions implemented by those laboratories.

7.8.1.3 Performance Evaluation Program

The Lead Chemist is responsible for requesting and maintaining an appropriate inventory of PE samples and for obtaining all pertinent information regarding their identification and content in accordance with the EPA Region I Performance Evaluation Program Guidance, July 1996, Revision (Attachment H) or most recent revision. The Lead Chemist must ensure that a single blind PE sample is included, whenever available, with every sample delivery group sent to a laboratory for each matrix, analytical parameter, and concentration level.

Upon receipt of the laboratory data package, the Lead Chemist is responsible for submitting to the EPA PE Chemist a copy of the tabulated PE sample results for scoring for those PE samples provided by EPA.

The PES Score Reports for EPA-provided PE samples and PE results for PE samples procured from commercial vendors must be evaluated with the laboratory data package during data validation. If only

a Tier I validation is performed, the PES Score Reports for EPA-provided PE samples and PE results for PE samples procured from commercial vendors are evaluated in addition to performing the Completeness Evidence Audit.

7.8.1.4 Tracking Data Package Delivery

If a CLP data package is late, then the Lead Chemist is responsible for alerting the EPA RSCC. If the EPA RSCC is unable to resolve late data delivery within 2 weeks, the RSCC will contact the CLP-TPO to expedite problem resolution.

If data are late from a non-CLP laboratory subcontracted by an EPA Field Sampling Contractor, then the Lead Chemist should contact the laboratory to ascertain the problem and confirm a delivery date. Similarly, if data are late from the Contractor's own internal laboratory, then the Lead Chemist should contact the laboratory to ascertain the problem and confirm a delivery date. In both cases, the Lead Chemist is responsible for expediting late data.

7.8.1.5 Data Validation

The Lead Chemist is responsible for providing a copy of the project DQO Summary Form, the field sampling notes, the technical specifications for non-CLP analyses, the PES Score Reports and/or the QC acceptance ranges for commercial PE samples, and any Telephone Logs/Communication Forms generated prior to data validation to the data validator.

The Lead Chemist is responsible for reviewing and approving all Data Validation Memoranda written by corporate and subcontracted data validators. The Lead Chemist is responsible for all statements that their validators make in the Data Validation Memorandum concerning the final data assessments including the limitations and potential uses of validated data.

The Lead Chemist, as a designated Regional CLP representative, is responsible for contacting the laboratory to obtain necessary data resubmissions for non-compliant CLP data. They must adhere to the EPA-NE policy for contacting the laboratory, must document in Telephone Logs/Communication Forms all requests for data resubmissions and time frames, and must transmit copies of the Telephone Logs/Communication Forms to appropriate locations. Refer to the procedures in Section 9.1, The Regional/Laboratory

Communication Network.

The Lead Chemist ensures that a Data Validation Report or a Tier I Validation Cover Letter is delivered to the EPA Site Manager within 21 days of the receipt of a data package from the laboratory or in accordance with the pre-approved site schedule. Expected delays in the delivery of the validation reports must be reported to the EPA Site Manager.

The Lead Chemist ensures that Fund-lead and PRP/Federal Facility oversight CLP and non-CLP Data Validation Reports (Tiers II and III) and Tier I Validation Cover Letters are correctly distributed within EPA-NE and to other Regions. See Section 13.0 for the list of recipients and correct distribution.

7.8.1.6 Reduced Payment/Data Rejection Recommendations

It is the responsibility of the EPA Field Sampling Contractor's Lead Chemist to ensure that all contractual defects and unresolved deliverable deficiencies are noted in the Data Validation Memorandum and on the ORDA/IRDA Form.

Any CLP or EPA-generated non-CLP data that are deemed to be contractually non-compliant (based on laboratory analytical technical specification) and unusable in making site decisions should be recommended for rejection, returned to the laboratory and payment denied. In this case, sample results are reported as "rejected" to the EPA Site Manager in the Data Validation Report. If only one analytical fraction is rejected, then only the data for that fraction should be returned to the laboratory and the remaining fractions should be validated in accordance with the guidance provided in Parts II - IV.

Any CLP or EPA-generated non-CLP data that are deemed to be contractually non-compliant and of reduced worth to the Region in terms of making site decisions should be recommended for reduced payment. In this case, sample results should be qualified in accordance with the guidance provided in Parts II-IV of this document.

7.8.1.6.1 CLP Data

The Lead Chemist is responsible for notifying the EPA Data Validation Chemist when CLP data are contractually non-compliant and unusable, in accordance with EPA-NE Standard Operating Procedures for Submitting Data for Reduced Payment/Data Rejection, September 1991 (Attachment I) or most recent revision

and in accordance with the Federal Acquisition Regulation (FAR). The Lead Chemist is responsible for providing to the EPA Data Validation Chemist a letter describing the contractual non-compliances and providing supporting documentation within the time frame specified in the SOP mentioned above.

7.8.1.6.2 EPA-Generated Non-CLP Data (i.e., DAS Data)

The Lead Chemist is responsible for documenting contractual non-compliances, determining if they affect the potential usability of the data, and ensuring that EPA does not pay for unusable, non-compliant EPA-generated non-CLP data.

7.8.1.7 Data Validation Oversight and Implementation of Corrective Action

The Lead Chemist is responsible for responding to all requests for data validation oversight by the Region. The Lead Chemist reviews the "EPA-NE-generated Data Validation Oversight/Methods Review Memoranda" and directs the implementation of appropriate corrective actions. Subsequently, the Lead Chemist monitors the implementation and is responsible for the continued effectiveness of all corrective actions.

7.8.1.8 Qualifications of the Lead Chemist

The Lead Chemist should have a B.S. degree in chemistry or a related physical science and be a professionally trained analytical chemist with at least eight to ten years of combined inorganic and organic analytical experience which includes familiarity with GC/MS and ICP instrumentation. The Lead Chemist should have extensive knowledge of CLP methods, deliverables, and program operation as well as extensive knowledge of all other EPA program analytical methodologies, i.e., RCRA SW 846 methods, Drinking Water Program 500 series methods, ambient air and stack testing, etc., to enable them to recommend the appropriate methods and modifications for those methods for achieving project DQOs.

The Lead Chemist should have extensive knowledge of the most recent EPA-NE validation requirements, as specified in this document. The Lead Chemist must be technically able to identify the need to modify validation criteria when non-CLP analyses are performed and must be able to incorporate and document the modified validation criteria into an EPA-approved QAPjP and/or SAP.

7.8.2 Data Validator

This section specifically details the responsibilities of the EPA Field Sampling Contractor's data validator performing validation on data generated for Fund-lead sites or EPA oversight activities. However, many of the activities, roles, responsibilities and qualifications discussed below are applicable to non Fund-lead work performed by a PRP or Federal Facility as well as to Fund-lead work performed by another Federal Agency (i.e., ACOE) or a State.

7.8.2.1 Data Validation

Data validators must assess the analytical deficiencies and contractual non-compliances of a data package in accordance with the most recent revision of the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses. They are responsible for using modified validation criteria when required by an EPA-approved QAPjP and/or SAP.

The data validator is responsible for obtaining resubmittals for non-compliant data from the laboratory. In the CLP system, only designated regional communication representatives may contact a CLP Laboratory (usually the Lead Chemist), therefore the data validator must contact the laboratory through their designated CLP communication representative or alternate.

The validator reviews the Data Quality Objectives for the project as documented in the QAPjP or SAP and DQO Summary Form and determines if the degree of "measurement error" associated with the data potentially compromises data usability. The driving force for data validation is that contractually compliant data are not always technically usable for making site decisions and that contractually non-compliant data are sometimes very usable. **Only the end user can determine actual usability of the data.**

The data validator must notify the Lead Chemist immediately if significant contractual deficiencies warrant recommendation for data rejection or reduced payment.

The data validator is responsible for using the appropriate DQO Summary Form and should contact the Lead Chemist if this document has not been provided.

The data validator must contact field samplers whenever necessary to obtain information to assess "sampling error". All communications must be documented in a Telephone Log/Communication Form and included in the Data Validation Report. If a copy of the field sampling notes was not provided,

then the data validator should contact the Lead Chemist to obtain the notes.

The data validator must have the technical specifications for non-CLP analyses and any additional data quality criteria specified in the QAPjP or SAP in order to validate non-CLP data. If the technical specifications for non-CLP analyses and additional data quality criteria were not provided, then the data validator should contact the Lead Chemist to obtain the applicable technical specifications and data quality criteria.

The data validator must obtain the PES Score Reports for CLP and non-CLP analyses in order to validate the sample data. If PES Score Reports were not provided, then the data validator should contact the Lead Chemist to obtain the applicable PES Score Reports. If commercial PE samples were used, then the data validator should obtain the vendor's QC acceptance limits from the Lead Chemist in order to evaluate the PE sample results.

The data validator must obtain any Telephone Logs/Communication Forms generated prior to data validation for CLP and non-CLP analyses in order to validate sample data. If any Telephone Logs/Communication Forms generated prior to data validation for CLP or non-CLP analyses were not provided, then the data validator should contact the Lead Chemist to obtain any applicable Telephone Logs/Communication Forms generated prior to data validation.

The data validator generates a Tier I Validation Cover Letter with the following attachments in the order specified below: (Refer to Section 10 for complete description of Tier I Validation Cover Letter).

1. Cover Letter
2. Attachments

a. CADRE-generated Data Summary Table of Unvalidated Data (not required if CADRE Review not performed)
b. Data Validation Worksheet XI-Accuracy Check and EPA PE Score Reports and/or non-EPA PES results with Vendor PES QC Acceptance Limits
c. Support Documentation
    i. Copy of non-CLP analytical method, e.g., DAS methods, modified EPA methods
    ii. Copies of Telephone Logs/Communication Forms for:
        - RSCC communications
        - Requests for laboratory data resubmissions/ clarifications
        - Communications with samplers resolving sampling problems
        - Communications with TPO/Lead Chemist to report contractually-deficient data for rejection/reduced payment
        - Communications with EPA Site Manager concerning possible data rejection
        - EPA Site Manager authorization for alternate DV tier
    iii. Copies of data supporting recommendations for reduced payment resulting from CSF Audit and/or PE sample result evaluation
    iv. Original data to support recommendations for data rejection/non-payment resulting from CSF Audit and/or PE sample result evaluation
    v. Copies of field sampling notes and/or field report supplied by field sampler
    vi. Copies of EPA-approved amendments to QAPjP and/or SAP describing modified criteria to be used for validating site data
d. CSF Completeness Evidence Audit
e. DQO Summary Form

The data validator generates a Data Validation Report, applicable to Data Validation Tiers II and III, that consists of the following components in the order specified below: (Refer to Section 11 for a description of each of the Data Validation Report components).

1. Organic Regional Data Assessment/Inorganic Regional Data Assessment
   (ORDA/IRDA) Form
2. Data Validation Memorandum
   a. Narrative
   b. Table I-Qualifier Recommendation Summary Table
   c. Table II-Overall Evaluation of Data
   d. Table III-Tentatively Identified Compounds
   e. Data Summary Tables
3. Standard Data Validation Worksheets
   a. Manual
   b. Automated Data Review Reports (i.e., CADRE)
4. Support Documentation
   a. Copy of non-CLP analytical method, e.g., DAS methods, modified EPA methods
   b. Copies of EPA PES Score Reports and/or non-EPA PES results with Vendor PES QC Acceptance Limits
   c. Copies of Telephone Logs/Communication Forms for:
      - RSCC communications
      - Requests for laboratory data resubmissions/clarifications
      - Communications with samplers resolving sampling problems
      - Communications with TPO/Lead Chemist to report contractually-deficient data for rejection/reduced payment
      - Communications with EPA Site Manager concerning possible data rejection
      - EPA Site Manager authorization for alternate DV tier
   d. Copies of data supporting recommendations for reduced payment resulting from CSF Audit and/or PE sample result evaluation
   e. Original data to support recommendations for data rejection/non-payment identified from Tier II or Tier III data validation
   f. Copies of field sampling notes and/or field report supplied by field sampler
   g. Copies of EPA-approved amendments to QAPjP and/or SAP describing modified criteria to be used for validating site data
5. CSF Completeness Evidence Audit
6. DQO Summary Form

The data validator is responsible for implementing all corrective actions required by the contractor Lead Chemist in response to EPA-NE data validation oversight findings.

7.8.2.2 Qualifications of the Data Validator

7.8.2.2.1 Senior Validator

The senior data validator should have a B.S. or B.A. degree in chemistry or a related physical science and be a trained analytical chemist specializing in a particular discipline such as GC pesticides, GC/MS organics, or ICP metals. The validator should have at least five years of related analytical/instrumentation experience working with laboratory instrumentation and analyzing multi-media environmental samples (soil, water, oil, waste, fly ash, biological tissue and air). Data validation experience cannot be substituted for any of the five years required laboratory experience.

The senior validator should have extensive knowledge of the most recent EPA-NE validation requirements as specified in this document. The validator must also be capable of applying modified validation criteria when required by the EPA-approved QAPjP and/or SAP.

All Data Validation Reports must undergo internal peer review by the organization performing the validation. A senior validator must perform secondary review of all Data Validation Reports prepared by junior validators. If a senior validator prepares a Data Validation Report, then a different senior validator or other qualified senior chemist must peer review that Report.

7.8.2.2.2 Junior Validator

The junior validator should have a B.S. or B.A. degree in chemistry or a related physical science and be a trained analytical chemist specializing in a particular discipline such as GC pesticides, GC/MS organics, or ICP metals. The validator should have at least two years of related analytical/instrumentation experience working with laboratory instrumentation and analyzing multi-media environmental samples (soil, water, oil, waste, fly ash, biological tissue and air). Data validation experience may be substituted for some of the two years of required laboratory experience. However, the junior validator must have at least six months of instrumentation experience in the areas described above.

The junior validator should have extensive knowledge of the most recent EPA-NE validation requirements as specified in this document. The validator must also be capable of applying modified validation criteria when required by the EPA-approved QAPjP and/or SAP.

8.0 INFORMATION REVIEWED DURING THE DATA VALIDATION PROCESS

Figures 1, 2 and 3 illustrate the normal flow of the data validation process. Sources of information are noted, as well as communication channels and key decision points in the validation process. To evaluate data quality and the extent of "measurement error", the following items must be incorporated into the review of sample data: project scoping information documented in the EPA-approved SAP and/or QAPjP; analytical results presented in the laboratory data package; field sampling information; Contract Compliance Screening results; and Performance Evaluation Sample results.

8.1 Project Scoping Information

8.1.1 Objective

The QAPjP and/or SAP is a planning document that provides project history and background data and documents the project DQOs and sample custody procedures, evidentiary requirements, analytical methods, laboratory QA/QC, laboratory documentation and deliverables, and data validation criteria and validation tier to be used for the project. **These items should be agreed upon by all end users in the initial planning phase of the project.**

8.1.2 Requirements

The DQOs should be fully discussed and documented in the EPA-approved QAPjP and/or SAP and identified in abbreviated format in a DQO Summary Form. A copy of the SAP and/or QAPjP should be available to the validator and should include: the data validation criteria to be used (refer to Figure 4), reference to the Tier level of validation to be performed, modified validation criteria to be used (if any) or alternate validation criteria, i.e., USATHAMA and split sample comparability criteria and decision trees to be used in assessing split sample analyses. Project documents should detail the exact number of samples, types of samples (field and QC), PE samples, sample matrices, sample locations/descriptions and knowledge of any positive detects from prior site sampling efforts. Background information on the site is essential to identifying potential usability issues. The EPA Site Manager or Field Sampling Contractor Site Manager are the best sources for additional site information.

8.1.3 Evaluation

a. The validator should ascertain from the EPA-approved QAPjP, SAP and/or DQO Summary Form which validation criteria were selected by the end users. The validator should ascertain

whether the validation criteria contained in the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses are to be used without modification to validate site data, or whether modified EPA-NE validation criteria are to be utilized. Also, the validator must ascertain from the project planning documents if alternate validation criteria, i.e., USATHAMA are to be used for data validation.

b. If the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses were selected as the validation criteria by the end user, then the data validator should ascertain from the EPA-approved QAPjP, SAP and/or DQO Summary Form, the validation tier that are to be used to evaluate the project data.

c. The validator should determine if the correct analytical method as cited in the EPA-approved SAP, QAPjP, and/or DQO Summary Form was used for analysis and if required detection/quantitation limits were achieved.

d. The validator should be familiar with the project DQOs, as summarized on the DQO Summary Form, in order to identify potential usability issues for the end users.

e. Comparability criteria for split sampling should be presented in the EPA-approved QAPjP and/or SAP. Split sampling analyses are performed for PRP/Federal Facility oversight using standardized EPA (full protocol) methods. Field screening confirmatory analyses are also performed using standardized EPA methods. The % Difference Criteria between data sets should be based on the following standard equations to ensure consistency in presenting and assessing split data. Note: Comparability criteria should be based on historical data generated for the site and should take into account associated field precision. Homogenous matrices may allow for lower % Difference Criteria while heterogeneous matrices may necessitate higher % Difference Criteria to be set. A discussion and justification for selection of comparability criteria should be included in the EPA-approved QAPjP and/or SAP.

Split Sampling Analyses

$$\text{Equation 3: \% Difference (Splits/Duplicates)} = \frac{C_1 - C_2}{\left(\frac{C_1 + C_2}{2}\right)} \times 100$$

C_1 = Concentration Determined by EPA Oversight Analysis

C_2 = Concentration Determined by PRP, Federal Facility, or State Analysis

Note that this equation assumes that values generated by EPA and those values generated by equivalent methods used by the PRP (or other entities) are equally accurate. While this may not always be true, the equation serves to standardize reporting conventions and to promote data comparability. Note that this equation retains the sign of the difference, thus absolute numbers are not used.

Confirmatory Analyses

$$\text{Equation 4: \% Difference (Confirmatory Analysis)} = \frac{C_1 - C_2}{C_1} \times 100$$

C_1 = Concentration Determined by Full Protocol Confirmatory Analysis

C_2 = Concentration Determined by Field Screening Analysis

Note that this equation assumes that values generated by the full protocol confirmatory method are more accurate than those generated by field screening methods. While this may not always be true, the equation serves to standardize reporting conventions and to promote data comparability. Note that this equation retains the sign of the difference, thus absolute numbers are not used.

8.1.4 Action

a. If no validation tier or an inappropriate validation tier has been referenced in the DQO Summary Form, then the validator should contact the Lead Chemist who will obtain clarification/direction from the EPA Site Manager. The validator and/or Lead Chemist should document this call in a Telephone Log. The validator should note in the first paragraph of the Data Validation Memorandum if, in the validator's opinion, the validation Tier selected during

project scoping does not meet the project DQOs.

b. i. If the EPA-approved QAPjP and/or SAP does not cite specific validation criteria, then the validator must validate site data according to the most recent revision of the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses. The validator should note in the first paragraph of the Data Validation Memorandum that the data has been validated in accordance with the most recent revision of the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses.

ii. If modified or alternate validation criteria have been described in an EPA-approved QAPjP and/or SAP, then the validator should note these modified or alternate validation criteria in the first paragraph of the Data Validation Memorandum and copies of the relevant QAPjP or SAP pages should be attached to the Memorandum as supporting documentation.

iii. Alternatively, if the validator determines that modified or alternate validation criteria are necessary to validate the site data in order to support project DQOs and/or the use of non-CLP methods and those criteria have not been included in the EPA-approved site QAPjP/SAP, then an amendment to the QAPjP or SAP must be submitted to EPA and approved prior to validation. The amendment should be noted in the first paragraph of the Data Validation Memorandum and a copy attached to the Memorandum as supporting documentation.

c. If the data are contractually compliant but unusable because the wrong analytical method was selected and/or utilized, then this should be noted in the Data Validation Memorandum and an alternative method should be identified for future site work.

d. If the DQO Summary Form was not provided, then the validator should contact the Lead Chemist to obtain the Form. If a DQO Summary Form was not completed prior to the sampling event, then this should be noted in the first paragraph of the Data Validation Memorandum.

e. If split sampling criteria for oversight analyses or field screening confirmatory criteria for confirmation analyses

have not been established, then the validator should contact the Lead Chemist who will obtain clarification/direction from the EPA Site Manager. The validator and/or Lead Chemist should document this call in a Telephone Log.

8.2 The Data Package

8.2.1 Objective

The CLP Complete SDG File (CSF) data package is designed to provide all necessary documentation to verify compliance with the Statement of Work (SOW) and to permit verification of the accuracy and defensibility of the reported results. It contains all the original data generated for the data package.

A non-CLP data package should also provide all necessary documentation to verify compliance with the analytical method and/or contracts/subcontracts to permit verification of the accuracy and defensibility of the reported results. It should contain all the original data generated for the data package.

8.2.2 Requirements

A list of the required CLP deliverables may be found in the appropriate CLP SOWs.

Required non-CLP deliverables may be found in the appropriate methods and/or contracts/subcontracts developed for the analytical service. Most data collection activities will require all original data and a complete case file purge. See Attachment G for Training Manual for Reviewing Laboratory Data Package Completeness, June 1994.

8.2.3 Evaluation

Procedures for the evaluation of specific deliverables are detailed in Parts II, III, and IV of this document.

8.2.4 Action

When contract-required information necessary for data validation is missing from the data package, then the validator should arrange for the Lead Chemist to contact the laboratory to obtain the omitted data according to the procedure referenced in Section 9.2.

Only authorized personnel that are designated Regional CLP

representatives may contact CLP laboratories. Only prime contractors may contact their subcontracted laboratories due to privity of contract.

8.3 Field Sampling Information

8.3.1 Field QA/QC Samples

8.3.1.1 Objective

Field QA/QC samples, such as trip blanks, equipment blanks, bottle blanks, and field duplicates enable data validators to identify some, but not all, of the "sampling error" associated with the project. Specifically, the field QA/QC assist the data validator in evaluating sampling conditions, techniques, field precision, and sample homogeneity.

8.3.1.2 Requirements

All field QA/QC sample requirements should support the project DQOs and should be documented in the EPA-approved QAPjP and/or SAP and DQO Summary Form.

At a minimum, equipment blanks and field duplicates must be included at a frequency of five percent per analytical parameter/matrix/sampling team.

At a minimum, volatile trip blanks are required at a frequency of one per shipment cooler.

At a minimum, temperature indicator blanks are required at a frequency of one per shipment cooler and should be clearly identified as temperature indicator blanks.

Bottle blanks are used to verify the cleanliness of a specific Lot Number of bottles and should be included at the discretion of the sampling team. At a minimum, bottle blank analyses should be performed on one bottle per container type per lot. The Lot Number for the bottle blank should be noted on the Traffic Report and/or Chain-of-Custody Form and in the field sampling notes.

8.3.1.3 Evaluation

Note that for large projects containing several sample delivery groups (SDGs) with many field samples and inter-related QC samples, the EPA Field Sampling Contractor may assign a Project Chemist to coordinate data collection and review. For large projects where the data validator alone may not be able to fully

assess field QA/QC compliance with the EPA-approved QAPjP and/or SAP, the assigned Project Chemist should review all the individual project Data Validation Reports to assess project compliance for field QA/QC requirements.

The validator should confirm that the required field QA/QC samples were provided to the laboratory at the proper frequency.

It is recommended that the results for each bottle blank (used to verify the cleanliness of a specific Lot Number of bottles) be evaluated prior to use of bottles from that Lot Number for field sampling.

The validator should evaluate contamination found in the equipment, trip and bottle blanks as part of the laboratory method blank review. Similarly, field duplicate precision should be evaluated concurrently with laboratory duplicate (MS/MSD) precision data to determine whether precision problems were laboratory or field related.

8.3.1.4 Action

a. If the field QA/QC samples were not provided to the laboratory in accordance with the frequency specified in the EPA-approved QAPjP/SAP, then the validator should note this deviation in the Data Validation Memorandum and the EPA Field Sampling Contractor should initiate corrective action procedures.

b. If the laboratory has not provided results for one or more of the samples that were shipped, the validator should check the Data Package Narrative and Telephone Logs/Communication Forms for a possible explanation (broken sample, insufficient sample volume for reanalysis, etc.). If no explanation is found, then the validator should contact the Lead Chemist who in turn contacts the RSCC to further investigate and resolve CLP issues. For non-CLP samples, the validator should contact the appropriate personnel to resolve the problems.

c. The field sampler must be informed immediately by the validator, and the call documented in a Telephone Log/Communication Form, if any of the following problems are noted:

   ! trip blanks, equipment blanks, bottle blanks or field duplicates are not identified on the Traffic

Report/Chain-of-Custody Form

- anomalies such as Traffic Report numbers being listed twice, etc.

- high contamination in equipment, trip, or bottle blanks that is not present in the laboratory blanks

8.3.2 Sample Descriptions

8.3.2.1 Objective

All sample locations should support the project DQOs and be documented in the EPA-approved QAPjP and/or SAP.

Sample descriptions/locations/sampling dates are necessary information for preparing the Data Summary Tables and for the evaluation of holding times. In addition, sample descriptions are useful as supplementary information for the consideration and discussion of matrix problems and chemical constituents identified in particular samples.

8.3.2.2 Requirements

All sample locations should be sampled and numbered in accordance with the EPA-approved QAPjP and/or SAP.

For CLP data packages, copies of properly completed Traffic Reports (Attachment J, Form vi) are mandatory deliverables.

Copies of Chain-of-Custody Forms (Attachment J, Form v) must be included in all non-CLP data packages and must contain the date of sampling, sample numbers, as well as the sampling locations.

The sampler or Project Chemist should provide a copy of the field sampling notes to the Lead Chemist or data validator to be included in the Data Validation Report. In situations where sampling events extend over a period of weeks producing two or more SDGs and generate numerous pages of field log book notes, the field notes should be copied only once, included in one Data Validation Report and that Data Validation Report should be referenced by Case, SDG, and date of Data Validation Report.

8.3.2.3 Evaluation

Again, note that for large projects containing several sample delivery groups (SDGs) with many field samples and interrelated QC samples, the EPA Field Sampling Contractor may assign a Project Chemist to coordinate data collection and review. For

large projects where the data validator alone may not be able to fully assess field QA/QC compliance with the EPA-approved QAPjP and/or SAP, the assigned Project Chemist should review all the individual project Data Validation Reports to assess project compliance for field QA/QC requirements.

The validator should confirm from the EPA-approved QAPjP and/or SAP and DQO Summary Form that all sample locations have been sampled and that there are sample results for all locations.

Traffic Reports and COC Forms must be compared for consistency with respect to the designation of quality control samples (blanks and duplicates) and the identification numbers for field samples.

The data validator is not responsible for evaluating field sampling notes. They are to be included in the Data Validation Report to be used by the end user to assess data usability and to support potential litigation.

8.3.2.4 Action

a. If sample locations are not sampled in accordance with the EPA-approved QAPjP and/or SAP, then the validator should note this deviation in the Data Validation Memorandum and the EPA Field Sampling Contractor should initiate corrective action procedures.

b. If discrepancies on the COC or Traffic Report Forms are identified, then the sampler must be contacted for resolution. The resolution must be documented in a Telephone Log (Attachment J, Form iii) and the Telephone Log must be included in the Data Validation Report.

c. If information is illegible (sample descriptions, locations, sampling date, etc.), then the sampler must be contacted to provide a legible copy of this information.

d. If Traffic Reports or COC Forms are missing, then the laboratory should be contacted to obtain this required deliverable. If the laboratory cannot provide this required deliverable, then the sampler must be contacted to provide a copy of these documents. If the Traffic Reports or COC Forms were not properly completed and/or signed by the laboratory personnel, then the laboratory must be contacted to obtain a written letter detailing the deficiency. This letter should be included in the CSF/data package as part of the site record and a copy included in the Data Validation Report.

e. If the field sampling notes are not provided prior to validation, then the validator must obtain a copy from the Lead Chemist for inclusion in the Data Validation Report.

8.4 CLP Laboratory Contract Compliance Screening (CCS)

8.4.1 Objective

CCS provides a high volume assessment of CLP deliverables for compliance with some, but not all, contract requirements. Its primary application is to determine payment recommendation. Because of this direct link to payment, CCS fosters a somewhat timely resolution of contractual problems.

8.4.2 Requirements

The NPO Sample Scheduling and Coordination Contract (currently named CLASS) performs CCS on all low/medium organic and inorganic data packages submitted through the CLP. Laboratories are required by EPA to submit all identified missing data, and resubmit or explain all data identified as non-compliant during CCS. To date, CCS has not been performed on CLP dioxin data packages. Also, CCS is not performed on EPA-generated non-CLP data.

8.4.3 Evaluation

CCS may be used, when available, during data validation to evaluate those technical criteria that are also contractual criteria and to determine the completeness of the data package. If available, CCS results should be previewed to determine important compliance issues. The validator should compare the findings of CCS to the laboratory data package in the course of data validation. An example regional CCS Report is contained in Attachment K.

8.4.4 Action

a. If the CCS information is not provided with the data package, it can be requested through the RSCC. CCS information is not necessary in order to perform validation because the validator assesses contractual compliance during the validation process.

b. If the CCS information indicates significant contractual non-compliance which coincides with poor technical quality and potentially limits the usability of the data, then the validator should recommend reduced payment or rejection of

data (See Attachment I).

c. When a contract-required reanalysis or deliverable was noted as missing by CCS, the validator should contact the laboratory to ascertain the expected delivery date.

8.5 Performance Evaluation Samples

8.5.1 Objective

The EPA-NE Performance Evaluation (PE) Program essentially serves three functions: (1) PE samples may be used in laboratory pre-award evaluations to identify a community of technically capable laboratories, (2) PE samples are used to evaluate laboratory performance over a period of time, (3) PE samples are included in a sample group to provide information on a laboratory's ability to accurately identify and quantitate analytes of interest during the period of sample analysis. In the third function, the PE program works in conjunction with the Region I Tiered Validation approach.

8.5.2 Requirements

EPA-NE established a Performance Evaluation Program on July 1, 1993. A copy of the most recent revision of the EPA Region I Performance Evaluation Program Guidance, July 1996, Revision, may be found in Attachment H. The document describes the purpose, use, quality assurance documentation requirements, responsibilities, and general procedures for utilization of the EPA-NE PE Program and includes a list of EPA-PE samples that are currently available through the EPA-NE QA Unit and a list of commercially available PE samples.

It is recommended that blind PE samples be included in each sample set sent to a laboratory, whenever appropriate, to assist in evaluating analytical data quality. One PE sample should be included for each sample matrix, parameter, and concentration level for each Sample Delivery Group (SDG) sent to a laboratory. The PE samples should be counted as field samples in the 20 sample SDG. The use of PE samples should be specified as a quality control measure at the planning stage of each project and documented in the EPA-approved QAPjP and/or SAP.

8.5.3 Evaluation

Upon receipt of the laboratory data package, the Lead Chemist or validator should determine if a PE sample was included for each sample matrix, parameter, and concentration level for each SDG sent to the laboratory. Next, the laboratory's EPA PE sample results must be submitted by the EPA Field Sampling Contractor

performing data validation to the EPA-NE PE Chemist for scoring. In the situation where data validation is performed by a subcontractor, only the prime contractor may submit PE results to EPA.

For Tier II and Tier III validations, the data validator must incorporate the EPA-PE sample score results into the evaluation of data in accordance with Section XI in Parts II, III and IV of this document.

For Tier I validations, EPA-PE sample results must also be scored and evaluated in accordance with the guidance noted above to determine whether laboratory problems exist and whether a higher validation tier is warranted based upon analytical problems identified by the PES.

If non-EPA (commercial) PE samples are reported in the data package, then the validator should assess the results of the PE samples based upon the vendor's QC acceptance limits in accordance with Section XI in Parts II, III, and IV of this document.

8.5.4 Action

a. If PE samples were not submitted by an EPA Field Sampling Contractor in accordance with the frequency requirements stated in the Region I policy, then the validator should note this deficiency in the Data Validation Memorandum. If an EPA Field Sampling Contractor consistently fails to comply with Region I policy, corrective action will be required.

b. If PE sample results are acceptable or do not indicate major laboratory performance problems, then the validator should complete the Tier I, II or Tier III validation.

c. If PE sample results indicate major laboratory performance problems and are unacceptable and a Tier II or Tier III validation was required, then the validation should be completed to ascertain the source of the analytical error. If the data quality is suspect, then the data should be recommended for reduced payment or, alternatively, rejected as unusable, returned to the laboratory and payment denied.

d. If PE sample results are unacceptable and a Tier I validation was required, then the validator should document this in the Tier I Data Validation Cover Letter and consider the need to upgrade the tier level to determine if

the data is unusable and should be rejected. The validator must receive authorization from the EPA Site Manager to upgrade the data validation tier prior to doing so. Authorization must be documented in a Telephone Log and included in the Tier I Validation Cover Letter, or (if the validation tier was upgraded) in the Data Validation Report.

8.6 Computer-Aided Data Review and Evaluation (CADRE) Reports

8.6.1 Objective

CADRE is a computer program that was developed to perform automated validation of organic and inorganic Low/Medium CLP data that have been entered into the national CLP Analytical Results Database (CARD). The automated review criteria are based on the USEPA CLP National Functional Guidelines for Organic Data Review, February 1994, and the USEPA CLP National Functional Guidelines for Inorganic Data Review, February 1994. In most cases, CADRE criteria are similar to Region I Tier II validation criteria. Where the criteria are different, the CADRE program has been customized for EPA-NE to incorporate EPA-NE Validation criteria. For those additional validation criteria, e.g. field duplicates, that are not assessed by CADRE, a Guidance Document for Completing Region I Data Validation Utilizing CADRE Data Review, February 1995 (Attachment L) is available to assist data validation completion.

Currently, this automated validation program is available only for EPA CLP Fund-lead and oversight use. However, in the future, computer-assisted data validation for EPA-generated non-CLP data may be available.

8.6.2 Requirements

Eventually, all EPA-NE CLP Organic and Inorganic Low/Medium SOW laboratory data packages will be validated using CADRE. Currently, CADRE reports for CLP Organic Low/Medium Volatile and Semivolatile analyses are provided to the EPA Field Sampling Contractor along with the CSF/CLP laboratory data package to assist in data validation.

8.6.3 Evaluation

Tier I validation does not include the review of CADRE Reports. The validator should include the CADRE-generated Data Summary Table of **NOT VALIDATED DATA** as an attachment to the Tier I Validation Cover Letter.

Tier II and III validations include the use of CADRE reports. Refer to the Guidance Document For Completing Region I Data Validation Utilizing CADRE Data Review, February 1995, or most recent revision for guidance on data validation completion in conjunction with CADRE review.

8.6.4 Action

Occasionally laboratory electronic deliverables are unavailable, incomplete or of such poor quality that they cannot be used by the CADRE program. If a Low/Medium Organic or Inorganic CLP CSF is received by the EPA Field Sampling Contractor from EPA without a CADRE report but with a notification that manual validation is required, then the EPA Field Sampling Contractor must perform manual validation for that CLP CSF.

If the CADRE report is incomplete, then the validator should contact the EPA DV Chemist to obtain the complete report.

9.0 COMMUNICATION NETWORKS

9.1 The CLP-Regional Sample Control Center (RSCC) Communication Network

9.1.1 Objective

9.1.1.1 CLP

The Regional Sample Control Center (RSCC) is synonymous with the Regional Sample Control Coordinator (RSCC) for EPA-New England. The RSCC places all regional requests for CLP sample analyses through the NPO Sample Scheduling and Coordination Contract (currently named CLASS). Requests for CLP analyses may be initiated by EPA Site Managers or Field Sampling Contractors doing Fund-lead or PRP/Federal Facility oversight, or States (or their contractors) performing Fund-lead work under Cooperative Agreements with EPA, or other Federal Agencies (or their contractors), i.e., the Army Corp of Engineers, performing Fund-lead work under Interagency Agreements.

The RSCC tracks CLP samples originating from Region I, regardless of the organization that collects them, in the New England Sample Tracking System (NESTS) database.

9.1.1.2 Non-CLP

The RSCC does not schedule non-CLP analytical services for EPA Field Sampling Contractors, States or other Federal Agencies. However, the RSCC schedules non-CLP analytical services that are obtained directly through any of EPA-New England's regional environmental analytical procurements.

The RSCC tracks all non-CLP samples collected by EPA Field Sampling Contractors doing Fund-lead or PRP/Federal Facility oversight work, i.e., through the DAS mechanism.

The RSCC does not track non-CLP samples collected by the States or other Federal Agencies doing Fund-lead work under Cooperative Agreements and Interagency Agreements, respectively.

9.1.2 Requirements

9.1.2.1 CLP

EPA Field Sampling Contractors must submit quarterly CLP sample projections to the RSCC. Completed DQO Summary Forms for each sampling event should accompany the quarterly sample projections and must be submitted prior to sampling. To reserve sample slots the EPA Field Sampling Contractor must follow the procedures outlined in 9.1.3.1.

States and Federal Agencies that utilize CLP for sample analysis must also submit quarterly CLP sample projections to the RSCC. Completed DQO Summary Forms for each sampling event must accompany the quarterly projections. To reserve sample slots States and other Federal Agencies must follow the procedures outlined in 9.1.3.1.

If EPA personnel will be collecting samples at a site for CLP analyses, then the Site Manager must notify the RSCC and submit a completed DQO Summary Form by 5:00 p.m. on the Tuesday before the scheduled sampling event.

9.1.2.2 Non-CLP

EPA Field Sampling Contractors that procure non-CLP analytical services, or use their own corporate laboratory to analyze non-CLP samples or use the EPA regional laboratory for non-CLP analyses must follow the sample tracking procedures referenced in 9.1.3.2. Completed DQO Summary Forms must be submitted to the RSCC prior to the sampling event.

States, other Federal Agencies, PRPs and Federal Facilities are not required to report non-CLP sample tracking information to the

EPA at this time. However, States, other Federal Agencies, PRPs and Federal Facilities should maintain non-CLP sample tracking information in their site files to assist EPA in tracking non-CLP data upon EPA's request.

9.1.3 Procedure

9.1.3.1 CLP

EPA Sampling Field Contractors, EPA Site Managers, States and other Federal Agencies requiring CLP services must contact the RSCC in accordance with The Regional Sample Control Center Guidance for The Contract Laboratory Program (CLP) and Delivery of Analytical Services (DAS) Program for EPA-New England, July 1996 (Attachment P).

9.1.3.2 Non-CLP

EPA Field Sampling Contractors that procure their own non-CLP analytical services, or obtain non-CLP services from their corporate laboratory or from the EPA-NE regional laboratory must report the sample tracking information to the RSCC in accordance with The Regional Sample Control Center Guidance for The Contract Laboratory Program (CLP) and Delivery of Analytical Services (DAS) Program for EPA-New England, July 1996 (Appendix P) and the DAS Sample Tracking and Scheduling Standard Operating Procedure, from the Region I ARCS Delivery of Analytical Services Pilot Program, Final Report, Volume II. Appendices, 15 March 1994, (Attachment Q).

States and other Federal Agencies that procure non-CLP analytical services or obtain non-CLP services from their organizations' own laboratory should schedule and track samples in accordance with their organizations' procedures.

9.1.4 Action

9.1.4.1 CLP

CLP analysis requests by an EPA Field Sampling Contractor, State or other Federal Agency must be made by 5:00 p.m. the Tuesday before sampling. If a request is made later than this time, sample analysis slots cannot be guaranteed. Also, if DQO Summary Forms are not submitted prior to the sampling date, sample analysis slots cannot be guaranteed.

If an EPA Field Sampling Contractor consistently fails to allow for sufficient lead time in scheduling CLP samples and/or fails

to accurately project quarterly CLP analytical needs, and/or fails to submit the associated DQO Summary Forms, corrective action will be required.

If a State or other Federal Agency performing Fund-lead work fails to allow for sufficient lead time in scheduling CLP samples and/or fails to submit the associated DQO Summary Forms, corrective action will be required.

9.1.4.2 Non-CLP

If an EPA Field Sampling Contractor, performing Fund-lead work or PRP/Federal Facility oversight, fails to provide the required non-CLP sample tracking information and/or the associated DQO Summary Form, corrective action will be required.

If States, other Federal Agencies, PRPs or Federal Facilities fail to schedule or track non-CLP samples correctly, corrective action should be initiated by that organization.

9.2 The Regional/Laboratory Communication Network

9.2.1 Objective

9.2.1.1 CLP

In January 1983, the CLP National Program Office established a system of direct communication between the regions and CLP laboratories as a routine method for regional data validation staff to obtain answers to technical questions concerning program data in the timeliest and most direct manner possible.

9.2.1.2 Non-CLP

EPA Field Sampling Contractors, States and other Federal Agencies performing Fund-lead work and/or PRP/Federal Facility oversight should establish a direct communication system with their contractor and/or subcontractor laboratories (as appropriate based upon privity of contract) to ensure timely resolution of technical issues.

For non Fund-lead sites, PRPs and Federal Facilities should also establish a direct communication system with their contractor and/or subcontractor laboratories (as appropriate based upon privity of contract) to ensure timely resolution of technical issues.

9.2.2 Requirements

The requirements for the CLP system are as follows:

a. Regional contact with CLP laboratories is permissible only after laboratory data submission.

b. Questions involving data delivery, contractual requirements, procedural recommendations, and other general CLP matters are to be referred to the RSCC, the NPO Sample Scheduling and Coordination Contract (currently named CLASS), or to program management (i.e., EPA-NE CLP-TPO) as appropriate.

c. Reanalysis requests originating from the data validator must be channeled by the EPA Field Sampling Contractor Lead Chemist through the EPA-NE CLP-TPO or EPA DV Chemist.

d. Only authorized personnel that are designated Regional CLP representatives may contact CLP laboratories, and they may contact only specified laboratory personnel.

To become a designated Regional CLP representative or alternate, the candidate's name and resume must be submitted to the CLP-TPO for review. Upon approval of the candidate, the CLP-TPO will notify CLASS for inclusion on the Region I CLP representatives list.

Similar requirements should exist for a non-CLP communication system.

9.2.3 Procedure

9.2.3.1 CLP

a. The entire data package should be assessed to determine if any of the four Action items listed below in Section 9.2.4 are a problem within the laboratory data package.

b. A list of required data resubmissions and analytical clarifications should be faxed to the laboratory prior to initiating the call.

c. The designated Regional CLP representative should call the laboratory, discuss each item on the faxed list, and

establish a due date for resubmissions. The time frame for resubmission should be limited to seven days.

d. All conversations between the regional representatives and the CLP laboratories should be recorded by both the laboratories and the regional representatives on the Telephone Log or Regional/Laboratory Communication Form (Attachment J, Form iii).

e. The original Telephone Log/Communication Form is included in the Data Validation Report or Tier I Validation Cover Letter sent to the EPA Site Manager. One copy of the Telephone Log/Communication Form is forwarded by the EPA Field Sampling Contractor to each of the following:

- EPA NPO Sample Scheduling and Coordination Contract (currently named CLASS)
- The EPA-NE CLP-TPO (their copy to be included in the Data Validation Report or Tier I Validation Cover Letter)
- The CLP laboratory
- EPA-NE RSCC

f. Resubmitted data should be marked as "additional data" by the CLP laboratory. All resubmitted and/or omitted data should be submitted to the Region accompanied by a revised DC-2 form.

g. If data resubmissions or verbal clarifications are not received within the specified timeframe, then the Regional CLP representative should contact the laboratory every day for 7 days.

h. If the information is still not received within the additional 7 days, then the Regional CLP representative should contact the CLP-TPO for follow-up action.

9.2.3.2 Non-CLP

a. For Fund-lead sites and PRP/Federal Facility oversight, all conversations between EPA personnel, EPA contractors, States, or other Federal Agencies with non-CLP laboratories should be recorded by both the non-CLP laboratories and the EPA/EPA Contractor/State/Other Federal Agency contacts.

b. For non Fund-lead sites, all conversations between PRPs, other Federal Agencies, or their contractors, with non-CLP

laboratories should be recorded by both the non-CLP laboratories and the PRP/Other Federal Agency/Contractor contacts.

c. Copies of the Telephone Log or Regional/Laboratory Communication Form should be:

- Included in the Data Validation Report or Tier I Validation Cover Letter
- Sent to the laboratory
- Retained in the site file

9.2.4 Action

The four types of problems that require direct contact between the designated Regional representatives and the laboratory for resolution of laboratory data package problems are illustrated in Figures 2 and 3 and are described below:

a. In the case of missing or illegible deliverables, the validator should contact the laboratory through their designated Regional CLP representative to establish and record the expected due date for the requested deliverables.

b. i. When a CLP contract required reanalysis, is missing, the validator should check the CCS report, if available, to see if the problem was noted. If so, the designated Regional CLP representative should contact the laboratory to ascertain the expected due date. If the problem was not noted by CCS, the validator and/or Lead Chemist, in conjunction with the EPA Site Manager, must decide whether initiation of a reanalysis request would provide usable data (weighing a consideration of holding times, etc.). To initiate a CLP reanalysis request, the validator or Lead Chemist must first contact the CLP-TPO or EPA DV Chemist. If the TPO deems reanalysis appropriate, a reanalysis request form will be forwarded by the TPO to the CLP-APO for that laboratory.

ii. When a non-CLP contract required reanalysis for Fund-lead and PRP/Federal Facility Oversight work is missing, the EPA Field Sampling Contractors, States and other Federal Agencies should contact their contractor and/or subcontractor laboratory (as appropriate based upon privity of contract) to ascertain the expected due date and ensure timely delivery of reanalysis results.

iii. When a non-CLP contract required reanalysis for non Fund-lead work is missing, the PRP, other Federal Agency, or their contractors should contact their contractor and/or subcontractor laboratory (as appropriate based upon privity of contract) to ascertain the expected due date and ensure timely delivery of reanalysis results.

c. Clarification of discrepancies or errors in the reported data usually requires correction and resubmission of results by the laboratory. If the laboratory does not agree with the error, then the validator should double check his/her work to ensure the accurate reporting and qualification of data. If the laboratory is still found to be in error but will not agree with the error, then the validator should use professional judgment to qualify the data.

d. In some cases, it may be necessary to have the laboratory provide certain explanations or detail conditions of analysis that do not correspond to any of the contract or method-required deliverables. In such cases, a verbal answer, documented in a Telephone Log/Communication Form by the designated Regional representative, is all that is contractually-required of the laboratory.

9.3 The CLP-TPO Communication Network

Similar to the communication networks described above, CLP-TPO communications involve contact with CLP Administrative Project Officers, CLP Contract Officers, CLP laboratories, the NPO contractors (CLASS and QATS) and the EPA Field Sampling Contractors' Lead Chemists. The CLP-TPO receives numerous QA reports from the NPO. Those which relate directly and specifically to CLP data validation will be forwarded to contractors responsible for data validation as appropriate.

Inter-regional questions or problems with CLP laboratory performance are referred to TPOs for resolution. For example, if a Region I data validator uncovers a possible contamination problem in a CLP laboratory assigned to Region II, the problem is first referred to the Region I CLP-TPO who then contacts the CLP-TPO in Region II to resolve the problem.

It is recommended that the CLP-TPO be notified of all problems and requirements for a particular case at one time. If there is an urgent requirement, the CLP-TPO may be contacted by phone to expedite corrective action. A copy of the Data Validation Report with the ORDA/IRDA Form as a cover page must be submitted to the CLP-TPO to provide documentation of the data validation and to facilitate resolution of inter-regional CLP laboratory performance problems.

10.0 THE TIER I VALIDATION COVER LETTER

10.1 Objective

The Tier I Validation Cover Letter documents that the data associated with a specific sample delivery group (SDG) were validated in accordance with the Region I Tier I Validation Guidance and justifies the use of a Tier I validation. The letter also documents the evaluation of PE sample results that were analyzed with the field samples, thereby providing a limited assessment of laboratory performance. Attachment M contains an example of a Tier I Validation Cover Letter.

10.2 Components of the Tier I Validation Cover Letter

10.2.1 Cover Letter

Tier I Validation Cover Letters that are generated for CLP Fund-lead and CLP PRP/Federal Facility oversight work, as well as EPA-generated non-CLP work, should be addressed and sent to the following:

- Christine Clark
  Regional Sample Control Center
  U.S. Environmental Protection Agency
  60 Westview Street
  Lexington, MA 02173
  cc: EPA Site Manager

- The subject heading of the Tier I Validation Cover Letter must include: the contractor work assignment number, the case number and SDG number (in that order), the laboratory name, the site name, the parameters evaluated, the total number of samples per sample matrix per parameter, (parenthetically identify the field duplicates), the sample matrix and field sample numbers analyzed for each parameter, the parameter, matrix and sample number for each type of blank, and the parameter, matrix, and sample number for each PE Sample. Note: Each sample number must be listed individually. (Refer to Attachment N for example of Data Validation Reports for exact Memorandum format to be used.)

- Only one SDG may be discussed in each Tier I Validation Cover Letter.

- Justification for Tier I validation. The validation Tier

is based on project DQOs and is determined by the end users at the time of project scoping.

! Evaluation of PE sample results and potential impact on data

10.2.2 Attachments

10.2.2.1 Data Summary Tables - Unvalidated Data (CADRE-generated spreadsheets)

Data Summary Tables clearly marked "**NOT VALIDATED DATA**" should be included as an attachment for all Low/Medium CLP Organic and Inorganic data that have undergone CADRE review.

NOTE: Data Summary Tables are not required for data that have not undergone CADRE review.

10.2.2.2 Accuracy Check Worksheet- Data Validation Worksheet XI and PES Score Report/Vendor PES QC Acceptance Limits

All SDGs are required to have a parameter/matrix/concentration level associated PE sample, if one is available. The PE sample results should be evaluated based on Section XI in the appropriate VOA/SV, PEST/PCB or Inorganic Functional Guidelines (Parts II, III and IV of this document).

10.2.2.3 Support Documentation

10.2.2.3.1 Analytical Method for Non-CLP Methods

Copies of non-CLP methods and modifications to standard methods should be included in the Tier I Validation Cover Letter as support documentation and identified as such.

10.2.2.3.2 Copies of Telephone Logs/Communication Forms for the following must be included in the Tier I Validation Cover Letter:

! All communications with RSCC to track data packages and to resolve sample scheduling, tracking, and shipment questions

! All Regional/Laboratory communications to laboratories requesting resubmittal and/or clarification of data

! All communications with samplers to clarify sample numbers, locations, descriptions or preservation techniques and/or to alert them to significant field contamination

- All communications with the CLP-TPO/EPA DV Chemist to report contractually-deficient CLP data that will be recommended for data rejection or reduced payment

- All communications with the EPA Site Manager concerning possible data rejection

- All communications with the EPA Site Manager to authorize change in required data validation tier.

10.2.2.3.3 Copies of Data Supporting Recommendations for Reduced Payment

All non-compliant data that are of limited use to the end user are deemed to be of reduced worth by the region and should be recommended for reduced payment.

All non-compliances identified during a Tier I Validation that adversely affect data usability should be documented by attaching tabulated laboratory forms, raw data, or validator-prepared tabulations to substantiate the findings and conclusions presented in the Tier I Validation Cover Letter. For CLP data, support documentation attachments should be numbered and/or labelled and referenced accordingly in the text of the Tier I Validation Cover Letter. Similarly, support documentation for unusable non-CLP data should be attached to the Tier I Validation Cover Letter and recommendation for reduced payment noted. In addition, the validator should circle the specific items of concern located on these attachments.

10.2.2.3.4 Original Data Supporting Recommendations for Data Rejection/Zero Payment

All non-compliant original data that are unusable by the end user are deemed contractually unacceptable to the region, and, therefore, the laboratory should not be paid. Original CLP data should be attached to the Tier I Validation Cover Letter and sent to the CLP-TPO/EPA DV Chemist with a cover letter recommending data rejection. Similarly, unusable non-CLP data should be attached to the Tier I Validation Cover Letter and returned to the laboratory for non-payment.

10.2.2.3.5 Copies of Field Sampling Notes and/or Field Report

The field sampling notes and/or field report should be provided by the field sampler to the Lead Chemist or data validator to be included in the Tier I Validation Cover Letter as an attachment.

In situations where sampling events extend over a period of weeks producing two or more SDGs and generate numerous pages of field log book notes, the field notes should be copied only once, included in one Data Validation Report and that Data Validation Report should be referenced by Case, SDG, and date of memorandum. The field sampling notes are included to provide complete documentation of the sampling event to substantiate site decisions made using the data and to support potential future litigation.

10.2.2.3.6 Copies of EPA-approved Amendments to QAPjP and/or SAP

Any EPA-approved amendments to the QAPjP and/or SAP that describe modified criteria used to validate site data should be included in the Tier I Validation Cover Letter as an attachment.

10.2.2.4 CSF Audit

Refer to Attachment C, Region I CSF Completeness Evidence Audit Program, July 3, 1991 or most recent revision.

10.2.2.5 DQO Summary Form

Copies of DQO Summary Forms previously submitted by the EPA Field Sampling Contractors, States and other Federal Agencies to the RSCC along with the quarterly CLP sample slot projections must be included with the Tier I Validation Cover Letter.

Copies of DQO Summary Forms for non-CLP sampling events previously submitted by the EPA Field Sampling Contractors to the RSCC prior to the sampling event, must be included with the Tier I Validation Cover Letter. Copies of DQO Summary Forms for non-CLP sampling events previously submitted by States and other Federal Agencies to the "Authorizing Organization" prior to the sampling event, should be included with site documents.

For proper distribution of the DQO Summary Forms refer to the DQO Summary Form Instructions (Attachment J, i).

The Draft DQO Summary Form (refer to Attachment J, i) should be used until such time as a Final version has been issued.

10.3 Initiating the Tier I Validation Procedure

a. Upon receipt of a data package, the data validator should ascertain the required data validation tier from the DQO Summary Form and/or EPA-approved QAPjP and/or SAP. If a Tier I

validation is required, then the validator should determine if EPA or commercial PE samples were analyzed with the SDG. If an EPA PE sample was analyzed, then the PE Form I results should be faxed to the EPA PE Chemist for scoring. If PE samples were obtained from a commercial vendor, then the vendor's PES QC acceptance limits should be utilized to evaluate PES results. If EPA or commercial PE samples were not included in the SDG, then the validator should note this and the reason why in the Tier I Validation Cover Letter.

b. The data validator should begin the Completeness Evidence Audit in accordance with the Region I CSF Completeness Evidence Audit Program, July 3, 1991 or most recent revision.

c. Once the PES Score Report is received, the data validator should evaluate the PE sample results in accordance with Section XI of Part II, III or IV of this document and complete the Section XI-Accuracy Check Worksheet.

d. The data validator should finalize the Completeness Evidence Audit.

e. If PE sample results indicate acceptable laboratory performance, then the validator should note this in the Tier I Validation Cover Letter.

f. If PE results indicate poor laboratory performance, then the data validator should note the specific laboratory performance problems and their impact on data quality. For example, "TCL MISSES" would indicate the possibility of false negatives, "TCL CONTAMINANTS" would indicate the possibility of false positives, and "ACTION LOW" and "ACTION HIGH" scores would indicate the possibility of negative and positive biases, respectively.

g. If PE results indicate poor laboratory performance, then the data validator should contact the EPA Site Manager to ascertain if a Tier II or Tier III validation is warranted. This call should be documented in a Telephone Log. **Only the EPA Site Manager can approve an upgrade in validation tier.**

h. The data validator should assemble the Tier I Validation Cover Letter with the all the required attachments as noted in Section 10.2.

11.0 THE DATA VALIDATION REPORT (Tiers II and III)

11.1 Objective

Data Validation Reports, generated for Tier II and Tier III validations, document that the data associated with a specific sample delivery group (SDG) were validated in accordance with the Region I Tier II and Tier III Validation Guidance, respectively. The Data Validation Report documents and discusses the rationale for any modifications to or deviations from the Region I Data Validation Guidance specified in this guidance document.

The findings of a Tier II and III validation are distributed to users for three distinct applications: (1) to make site decisions, (2) to provide oversight of CLP and non-CLP laboratory and method performance for contract management and payment recommendations, and (3) to provide EPA data validation oversight of the EPA Field Sampling Contractors.

For individuals involved in site-related decisions, it is imperative that the Data Validation Report present a clear explanation of those issues affecting the use of those data. The Report must provide the end users with an overview of analytical data quality and should also explain the qualitative confidence and quantitative "measurement error" associated with all sample results. In addition, the end users need Data Summary Tables that present all positive sample results, detection/quantitation limits, and associated qualifier codes.

On the other hand, the EPA individuals responsible for management and oversight of CLP and non-CLP laboratory performance and method performance require a presentation of issues related to laboratory non-compliance, poor laboratory practices that are not regulated in the contract, and any unusual method or analytical problems. For both contractual issues and problems affecting the usability of the data in making site decisions, support documentation must be sufficient to allow EPA to perform a full-scale review of the data validation in order to substantiate the Report's conclusions.

Data Validation Reports written by EPA Field Sampling Contractors are reviewed by the EPA-NE Quality Assurance Unit in accordance with the EPA-NE Data Validation Oversight/Methods Review Program. Data Validation Oversight Reports are provided to the EPA Site Managers and contract Project Officers. The contract Project Officer forwards the Data Validation Oversight Report to the EPA Field Sampling Contractor and requests corrective action. The continued effectiveness of the required corrective actions are monitored in subsequent validation oversights. Overall contractor data validation performance is monitored for each contract performance period.

11.2 Components of the Data Validation Report

In order to meet the varied needs of many end users, a six part **DATA VALIDATION REPORT** is generated. The report contains the following components in the order presented in this section. Each component should be completed in accordance with the following guidance. Attachment N includes two examples of Tier III Organic Data Validation Reports; a CLP Low/Medium organic soils SDG and a DAS low concentration surface waters SDG. Attachment J includes a copy of the following blank forms: DQO Summary Form, ORDA/IRDA Form, Telephone Log and Regional/Laboratory Communication Form, Data Validation Worksheets, Chain-of-Custody Form, and Traffic Report.

11.2.1 Organic/Inorganic Regional Data Assessment (ORDA/IRDA) Form

The ORDA/IRDA Form delineates issues relating to a laboratory's contractual non-compliance. The Form contains a checklist of items verified during validation. An ORDA/IRDA Form should be completed for all Tier II and III validations for CLP data validated by EPA Field Sampling Contractors, States, and other Federal Agencies for Fund-lead and PRP/Federal Facility oversight work. An ORDA/IRDA Form should also be completed for Tier II and III validations for non-CLP data performed by EPA Field Sampling Contractors for Fund-lead and PRP/Federal Facility oversight work.

For CLP data, "TPO/PO Action" should only be checked when contractual defects have resulted in reduced payment/data rejection recommendation letters to the TPO. All "TPO/PO Action" items should be detailed and documented in the "Action Items" line. Documentation supporting the "TPO/PO Action" items should be included in the Data Validation Report.

For EPA-generated non-CLP data, "TPO/PO Action" should only be checked when contractual defects have resulted in reduced payment/data rejection actions taken by the EPA Field Sampling Contractor. All "TPO/PO Action" items should be detailed and documented in the "Action Items" line. Supporting documentation should be included in the Data Validation Report. States, PRPs and other Federal Agencies are not required to submit ORDA/IRDA Forms for non-CLP data, but are encouraged to monitor the contractual performance of their contractor laboratories.

For both CLP and EPA-generated non-CLP data, refer to the back of the ORDA/IRDA Form for instructions on completing the form.

11.2.2 Data Validation Memorandum (DVM)

11.2.2.1 Narrative

This should briefly identify the scope of the analytical effort, provide a general overview of analytical quality, describe in detail and interpret all specific problem areas that were identified in the worksheets. Specific problems that impact the potential usability of the data should be emphasized. Data Validation Memoranda should be addressed and sent to the following:

- Christine Clark
  Regional Sample Control Center
  U.S. Environmental Protection Agency
  60 Westview Street
  Lexington, MA 02173
  cc: EPA Site Manager

  (Refer to Section 13.0 for proper distribution of Fund-lead, PRP/Federal Facility Oversight and EPA-generated non-CLP Data Validation Report copies. Data Validation Reports generated by PRPs, States or other Federal Agencies for non Fund-lead sites should be distributed in accordance with those organizations' requirements.)

- The subject heading of the DVM must include: the contractor work assignment number, the case number and SDG number (in that order), the laboratory name, the site name, the parameters evaluated, the total number of samples per sample matrix per parameter, (parenthetically identify the field duplicates), the sample matrix and field sample numbers analyzed for each parameter, the parameter, matrix and sample number for each type of blank, and the parameter, matrix, and sample number for each PE Sample. Note: Each sample number must be listed individually. (Refer to Attachment N for example of Data Validation Reports for exact Memorandum format to be used.)

- Only one SDG may be discussed in each Data Validation Report.

- The first sentence of the first paragraph should state the validation tier used to validate the sample data. If different tiers were used to validate different subsets of the SDG, then this should be noted and the associated subsets and tiers identified.

- The first paragraph must also state that the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses, July 1996 or most recent revision, was used to validate the data in accordance with the EPA-approved SAP and/or QAPjP. If validation criteria were modified to accommodate different QC criteria for non-CLP methods, then the modified criteria should be described in the first paragraph. If the EPA-approved SAP and/or QAPjP does not specify modified data validation criteria and the validator determines that modified criteria are necessary to properly evaluate the site data, then an amendment to the QAPjP and/or SAP describing the modified criteria must be submitted to EPA for approval prior to data validation. A copy of the amendment must be included in the support documentation for the Data Validation Report.

- The first paragraph must also identify the analytical methods used to analyze site samples.

- The second paragraph must list the QC parameters (checks) that were evaluated during validation. QC parameters that met criteria should be asterisked (*) in the left hand margin of the parameter name. Similarly, QC parameters that were not applicable to the analytical methods should be indicated by an "N/A" in the left hand margin of the parameter name. Note that worksheets should not be included for QC parameters that met criteria (except for Worksheet XII/XIII, Sample Quantitation) or were not applicable to the analytical method. (Refer to Attachment N for examples of a Tier II/III Data Validation Reports for exact memorandum format to be used.)

- "Potential Usability Issues" is the first parameter discussed in the DVM. The validator should discuss the potential impact of "measurement error" on data usability in terms of the project's Data Quality Objectives. The validator should cite the usable aspects of the data and should identify problems as having either a major or minor impact on data usability.

- The DVM should identify for each QC parameter that did not meet criteria the affected samples, the analytical problem, and the recommended actions.

- Information should be presented in tabular format whenever possible, (see example DVMs in Attachment N). Narratives should be limited to discussions of complex analytical problems and justifications of actions taken based on professional judgment. The information should be conveyed in simple, concise language that an individual without an extensive background in analytical chemistry can understand.

- The DVM must clearly differentiate problems affecting the confidence concerning the presence/absence of a compound versus those involving quantitative error.

- The DVM should also differentiate between sampling issues (sampling error) and analytical issues (analytical error).

- The narrative should list or reference all changes that the validator has made to the laboratory's reported data, whether due to misidentification, errors in transcription or calculation.

- The last QC parameter discussed in the DVM is System Performance. This should include an overview of interrelated and/or multiplicative analytical problems that impact usability of the data.

- The narrative should list support documentation attachments and should include the validator's name and signature.

11.2.2.2 Data Summary

11.2.2.2.1 Qualifier Recommendation Summary Table-Table I

The purpose of Table I is to identify all qualifier codes applied to each sample per parameter, taking into account the multiplicative effects of various qualifiers. The validator should assess tendencies in bias.

11.2.2.2.2 Overall Evaluation of Data (Data Validation Worksheet)-Table II

The purpose of Table II is to identify and summarize the "analytical error" associated with the data as well the "sampling error" that was identified through validation. It also identifies potential usability issues associated with the data

for the end user.

Since sampling variability must be assessed by the end user, that column remains blank on Table II throughout data validation.

11.2.2.2.3 Tentatively Identified Compound (TIC) Summary-Table III

Table III includes a list of TICs. TICs reported by the laboratory as "UNKNOWNS" without a compound class should not be included in the table.

11.2.2.2.4 Data Summary Tables-Spreadsheet

The purpose of the Data Summary Table is to provide a simple, condensed form of the analytical results (excluding PE sample results) for the end user, which enables a quick evaluation and comparison of the constituents identified at the various sampling locations.

Separate tables in "Lotus 1 2 3" are required for soil and water analyses and for organics and inorganics analyses. Additionally, separate tables are also required for volatile, semivolatile, and pesticide/PCB analytes for the organic analyses. Other database software may be used to generated Data Summary Tables as long as there is no deviation from the format and content requirements exhibited in Attachment N.

The Data Summary Tables must include: case number, CLP SDG number, site name, site location, matrix, parameter, concentration units, method-required detection/quantitation limits (CRDLs/CRQLs), EPA Sample (Traffic Report) numbers, sample locations/descriptions, laboratory sample numbers, all positive sample results, sample-specific and associated qualifier codes, dilution factors, % solids for soils, dates sampled, dates extracted, and dates analyzed. Examples of the Data Summary Tables are provided in Attachment N.

Only codes defined by this document are permitted to qualify data. Should it be necessary to include other codes, prior approval must be obtained from the EPA-NE CLP-TPO. If approval is given, complete definitions must be supplied in the key for the Data Summary Table. The standard data validation codes used in qualifying data in accordance with this guidance are:

U - The analyte was analyzed for, but was not detected. The

associated numerical value is the sample quantitation limit. The sample quantitation limit accounts for sample specific dilution factors and percent solids corrections or sample sizes that deviate from those required by the method.

J - The associated numerical value is an estimated quantity.

R - The data are unusable (analyte may or may not be present). Resampling and reanalysis is necessary for verification. The R replaces the numerical value or sample quantitation limit.

UJ - The analyte was analyzed for, but was not detected. The sample quantitation limit is an estimated quantity.

EB, TB, BB - An analyte that was identified in an aqueous equipment blank, trip blank, or bottle blank that was used to assess field contamination associated with soil/sediment samples. **These qualifiers are to be applied to soil/sediment sample results only.** (For additional guidance refer to Blank Section V of Parts II, III or IV)

11.2.3 Standard Data Validation Worksheets

The data validation worksheets included in this document must be utilized to perform the data validation. Any modification to the worksheets must be documented in the QAPjP and/or SAP and be approved by EPA prior to sampling.

Worksheets should not be included for QC parameters that meet criteria or criteria that are not applicable to the analytical method, except for Worksheet XII/XIII-Sample Quantitation. However, the data validator must complete page two of the Data Validation Worksheet Cover Page, and then sign and date the worksheet.

Copies of automated data review reports, i.e., CADRE, should be included in this section. Any automated data review reports, such as CADRE should be incorporated into the Data Validation Report according to the Guidance Document for Completing Region I Data Validation Utilizing CADRE Data Review, February 1995 or most recent revision.

A completed Data Validation Worksheet Cover Page must precede the other worksheets.

11.2.4 Support Documentation

11.2.4.1 Analytical Method for Non-CLP Methods

Copies of non-CLP methods and modifications to standard methods

should be included in the Data Validation Report as support documentation and identified as such.

11.2.4.2 Copies of Telephone Logs/Communication Forms for the following must be included in the Data Validation Report:

- All CLP "Records of Communications" with the RSCC to track data packages and to resolve sample scheduling, tracking, and shipment questions
- All Regional/Laboratory communications with laboratories requesting resubmittal and/or clarification of data
- All communications with samplers to clarify sample numbers, locations, descriptions or preservation techniques and/or to alert them to significant field contamination
- All communications with the CLP-TPO/EPA DV Chemist to report contractually-deficient CLP data that will be recommended for data rejection or reduced payment
- All communications with the EPA Site Manager concerning possible data rejection
- All communications with the EPA Site Manager to authorize change in required data validation tier.

11.2.4.3 Copies of Data Supporting Recommendations for Reduced Payment

All non-compliant data that are of limited use to the end user are deemed to be of reduced worth by the region and should be recommended for reduced payment.

All non-compliances, identified in the Data Validation Memorandum and/or on the ORDA/IRDA Form, that adversely affect data usability should be documented by attaching tabulated laboratory forms, raw data, or validator-prepared tabulations to substantiate the findings and conclusions presented in the text. Support documentation attachments should be numbered and/or labelled and referenced accordingly in the text of the DVM Narrative and on the ORDA/IRDA Form. In addition, the validator should circle the specific items of concern located on these attachments.

11.2.4.4 Original Data Supporting Recommendations for Data Rejection/Zero Payment

All non-compliant original data that are unusable by the end user are deemed contractually unacceptable and of no value to the region, and, therefore, the laboratory should not be paid. Original CLP data should be attached to the Data Validation Report and sent to the CLP-TPO/EPA DV Chemist with a cover letter recommending data rejection. Similarly, unusable, non-compliant non-CLP data should be attached to the Data Validation Report and returned to the laboratory for non-payment.

11.2.4.5 Copies of Field Sampling Notes and/or Field Report

The field sampling notes and/or field report should be provided by the field sampler to the Lead Chemist or data validator to be incorporated in the Data Validation Report as an attachment. In situations where sampling events extend over a period of weeks producing two or more SDGs and generate numerous pages of field log book notes, the field notes should be copied only once, included in one Data Validation Report and that Data Validation Report should be referenced by Case, SDG, and date of Data Validation Report. The field sampling notes are included to provide complete documentation of the sampling event to substantiate site decisions made using the data and to support potential future litigation.

11.2.4.6 Copies of EPA-approved Amendments to QAPjP and/or SAP

Any EPA-approved amendments to the QAPjP and/or SAP that describe modified criteria used to validate site data should be included in the Data Validation Report as support documentation.

11.2.5 CSF Completeness Evidence Audit

Refer to Section 10.2.2.4

11.2.6 DQO Summary Form

Refer to Section 10.2.2.5

11.3 Initiating the Tier II and Tier III Data Validation Process

Once the various sources of information, as discussed in Section 8, are assembled, the data validator should begin the Tier II or Tier III validation in accordance with steps a., b., and c. outlined in Section 10.3. Next, the validator should review the Data Package Narrative and generate Data Summary Tables in spreadsheet format (i.e., Lotus or other database software) according to the following guidance.

11.3.1 Reviewing the CLP Data Package Narrative/Cover Page

Review of the Data Package Narrative in conjunction with the chain-of-custody forms, Traffic Reports and Log In sheets (CLP Organic SDG Narrative or CLP Inorganic Cover Page) should quickly familiarize the data validator with all QC, sample, shipment and/or analytical problems.

The CLP Data Package (SDG) Narrative/Cover Page must:

- Justify the use of flagged edits on organic CLP quantitation lists.
- Document all instances of manual integration in organic CLP cases.
- Differentiate between initial analyses and reanalyses for CLP and state if reanalysis is billable and why.
- List all pH determinations for VOAs.
- Document SOW number or method name and version date.
- Be signed by the Laboratory Manager authorizing the release of the data, and verifying the contents of the data and deliverables.

Note: Non-CLP laboratory data packages should provide similar sample analysis information in a narrative or cover page format..

Review the Data Package Narrative/Cover Page to determine if gross analytical and/or shipment problems occurred.

If holding times were exceeded and resulted in qualified data, the data validator should assess the reduced worth of the data. For CLP data packages, the validator should submit a reduced payment recommendation to the TPO in accordance with Attachment O, March 7, 1995 Memorandum to Heidi Horahan, ARCS DPO re: CLP-SOW OLM03.1-New Contract Requirements. If holding times were grossly violated, then data rejection may be warranted. The data rejection procedures specified in Attachment I should be followed. If VOA sample pH measurements indicate that samples were not acid preserved in the field, then the validator should contact the sampler to confirm that incorrect preservation techniques were used and document the finding as "sampling error" in the Data Validation Memorandum.

If other analytical and/or sampling related problems, i.e.,

shipment, were noted in the Data Package Narrative, then the validator should describe in the DVM those problems that impact the potential usability of the data.

11.3.2 Generating Data Summary Tables

Transcribe the results from the Form Is onto the Data Summary Tables. For organic analyses, do not transcribe the qualification codes used by the laboratory except for all "U"s for non-detects as well as "J"s for positive detects reported below the sample-specific CRQL. For inorganic analyses, do not transcribe the qualification codes used by the laboratory except for all "U"s for non-detects. For all inorganic positive detects that are less than or equal to 2x analyte IDLs, qualify sample results with a "J" code.

As appropriate, information will be added to or deleted from the Data Summary Tables during the course of data validation. PES and method blank results should not be reported on the Data Summary Tables.

Note that for CADRE validations, the Data Summary Tables are automatically generated. CADRE Data Summary Tables are provided to the EPA data validator for both validated and unvalidated data. For Tier I validations, Data Summary Tables with "**NOT VALIDATED DATA**" are included as an attachment to the Tier I Validation Cover Letter. For Tiers II and III, the validator must complete the validation in accordance with the Guidance Document for Completing Region I Data Validation Utilizing CADRE Data Review, February 1995 or latest revision.

11.3.3 Usage of Qualifier Codes on the Data Summary Tables

The data qualifier codes, presented in Section 11.2.2.2.4, identify the degree of confidence concerning the presence or absence of reported compounds and identify results that are considered to be quantitatively inaccurate. These codes have been regionally standardized to ensure that data validators throughout the region employ the same set of simple, concise definitions that are understandable to personnel within the various EPA offices. Therefore,

a. Only codes defined in Section 11.2.2.2.4 may be used to qualify or reject data. Should it be necessary to include other codes, prior approval must be obtained from the EPA-NE CLP-TPO.

b. In general, only one qualifier code is used with each

reported result. The following hierarchy has been developed to ensure that only the most important code is used in situations where more than one quality control problem is associated with an analytical result:

- **!** Codes relating to identification take precedence over codes related to quantitation. **If results are rejected, replace the numerical sample result or sample quantitation limit with an "R".** Thus, whenever a positive result is rejected "R", the "J" code will not be used. Also, whenever a non-detected result is rejected "R", the "U" or "UJ" code will not be used.

- **!** Within each of the two categories of codes, the code that indicates a more serious problem with the data takes precedence. In all cases, the R code supersedes the J or EB, TB, BB codes.

- **!** The J and the EB, TB, BB codes may be used together for soil/sediment samples.

c. The above restriction on the general use of multiple qualifiers for a single result is applicable only to the Data Summary Table and not to the narrative portion of the Data Validation Memorandum. The narrative should mention all problems, major and minor, associated with the individual sample results.

d. Parts II, III and IV of this document address the individual situations requiring the use of particular qualifier codes. Upon completion of the data validation, the validator should double check the Data Summary Tables for accuracy and completeness to ensure that the appropriate qualifier codes were added according to the requirements listed herein. The validator should also check that there are no discrepancies between the worksheets, Data Validation Memorandum narrative, the Qualifier Recommendation Summary Table, and the Data Summary Tables.

Once the data validation has been completed, the validator compiles the Data Validation Report and submits it for internal review within their organization.

12.0 INTERNAL REVIEW OF VALIDATION DOCUMENTS

12.1 Senior Validator Review

A Senior validator should review all Tier I Validation Cover Letters and Data Validation Reports to ensure the following:

a. All components of a Tier I Validation Cover Letter or Tier II or Tier III Data Validation Report are included.

b. Data validation has been performed in accordance with the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses and/or EPA-approved modified or alternate validation criteria.

c. The data package has been evaluated for analytical quality and contractual compliance, and correct actions have been taken in the Data Validation Memorandum to address specific analytical deficiencies.

d. Compound names and concentrations reported on Data Summary Tables are consistent with Form I's or other laboratory tabulated report forms. All discrepancies should be justified in the Data Validation Memorandum.

e. Data qualifications identified in the worksheets are consistent with those in the Data Validation Memorandum narrative, the Qualifier Recommendation Summary Table and Data Summary Tables.

f. Non-compliant data that are unusable have been recommended for reduced payment/data rejection when applicable.

g. The project DQOs were used to determine if the degree of "measurement error" associated with the data potentially compromises the data usability.

12.2 Lead Chemist Review

As a final step in this process, it is important that the Lead Chemist check all outgoing reports for accuracy and completeness, due to the complexity of data validation and the importance of performing an accurate final assessment of data quality. The Lead Chemist must also review and concur with the final assessment of data quality and potential usability issues raised by the junior and senior validators.

The Lead Chemist should ensure that all accepted data are contractually compliant and usable.
The Lead Chemist must submit data rejection and reduced payment recommendation letters whenever appropriate.

The Lead Chemist must ensure that the final Data Validation Report is correctly distributed.

13.0 DISTRIBUTION OF DATA VALIDATION REPORTS AND TIER I VALIDATION COVER LETTERS

The following distribution table is applicable to Data Validation Reports and Tier I Validation Cover Letters generated by EPA Field Sampling Contractors for CLP and non-CLP Fund-lead and CLP PRP/Federal Facility oversight work.

The CLP Data Validation Reports generated by States or other Federal Agencies performing Fund-lead work under Cooperative and Interagency Agreements, respectively, should be sent to the EPA-NE RSCC for purposes of contract administration. A copy of the CLP Data Validation Reports and/or Final Project Reports should also be sent to the EPA Site Manager.

Copies of non-CLP Data Validation Reports generated by States, other Federal Agencies, PRPs, or Federal Facilities are not required to be forwarded to the EPA-NE RSCC. However, States, other Federal Agencies, PRPs, or Federal Facilities should forward a copy of the non-CLP Data Validation Report and/or the Final Project Report to the EPA Site Manager.

Table of Deliverables

Document	REGIONAL RECIPIENTS		NATIONAL RECIPIENTS
	EPA-NE		Regions II-X
	CLP-TPO/RSCC (For Central Files)	EPA SITE MANAGER	CLP-TPO
TIER I VALIDATION COVER LETTER with attachments	X	X	
DATA VALIDATION REPORT			
ORDA/IRDA Form	X		X*
DV Memo (including narrative, Tables I, II, III, and Data Summary Tables)	X	X	X*
	X	X	
Worksheets	X	X	X*
Support Documentation	X	X	
CSF Completeness Audit	X	X	
DQO Summary Form			
CSF - DATA PACKAGE		X**	

* CLP Data Validation Memoranda only (EPA-generated non-CLP Data Validation Memoranda are not distributed nationally)

Note: Telephone Logs/Communication Forms for the CLP Regional/Laboratory communication program should be forwarded to the NPO Sample Scheduling and Coordination Contractor, RSCC, CLP-TPO (their copy to be included in the Data Validation Report or the Tier I Cover Letter), and the CLP laboratory.

**All data packages/CSFs are ultimately archived in the EPA-NE Administrative Records Center.

14.0 EPA DATA VALIDATION OVERSIGHT/METHODS REVIEW PROGRAM

The regional QA Unit of OEME reviews and comments upon contractor-prepared Data Validation Reports and Tier I Validation Cover Letters. This oversight program serves a dual purpose. First, the QA Unit evaluates the contractor's ability to accurately perform data validation in accordance with this regional policy. Secondly, the QA Unit assesses the use of current, new and/or modified analytical methods in order to make needed method revisions based on scientific data. Resubmission of Data Validation Reports may be required in cases where the required format and procedures were not followed, or when clarifications or corrections are needed. The EPA Field Sampling Contractor is responsible for implementing and monitoring the effectiveness of all corrective actions recommended by EPA during oversight for validations performed by the prime contractor and any subcontractors. When critical deficiencies and/or problems have been identified during EPA Oversight, the EPA Field Sampling Contractor may be required to prepare a separate Corrective Action response letter to resolve those deficiencies and/or problems.

References

1. User's Guide to the Contract Laboratory Program, EPA/540/P-91/002, January 1991.

2. EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5, August 1994, DRAFT INTERIM FINAL.

3. NEIC Policies and Procedures, EPA-330/9-78-001-R, May 1978, revised May 1986.

4. Data Quality Objectives Process for Superfund, EPA/540/R-93/071, September 1993, INTERIM FINAL.

5. Test Methods for Evaluating Solid Waste, Physical/Chemical Method (EPA Pub. SW-846, Third Edition) and updates.

6. USEPA Contract Laboratory Program Statement of Work for Inorganic Analysis, ILMO4.0, EPA/540/R-95/121.

7. USEPA Contract Laboratory Program Statement of Work for Organic Analysis, OLMO3.1, EPA/540/R-94/073.

8. Region I Tiered Organic and Inorganic Data Validation Guidelines, July 1, 1993, DRAFT.

9. Region I CSF Completeness Evidence Audit Program, July 3, 1991.

10. Region I Laboratory Data Validation Functional Guidelines for Evaluating Organics Analyses, 2/01/88, modified 11/01/88.

11. Region I Laboratory Data Validation Functional Guidelines for Evaluating Inorganics Analyses, 6/13/88, modified 2/89.

12. Specifications and Guidance for Contaminant-Free Sample Containers - Publication 9240.0-05A, EPA/540/R-93/051, December 1992.

13. Preparation of Soil Sampling Protocols: Sampling Techniques and Strategies, EPA/600/R-92/128, July 1992.

14. Guidance Document for Completing Region I Data Validation Utilizing CADRE Data Review, February 1995.

15. USEPA Contract Laboratory Program National Functional Guidelines for Organic Data Review, EPA/540/R-94/012, February 1994.

16. USEPA Contract Laboratory Program National Functional Guidelines for Inorganic Data Review, EPA/540/R-94/013, February 1994.

17. EPA Region I Performance Evaluation Program Guidance, July 1996 Revision.

18. Standard Operation Procedures for Submitting Data for Reduced Payment/Data Rejection, September 9, 1991.

19. Training Manual for Reviewing Laboratory Data Package Completeness, June 1994.

Part I - Data Validation Manual: The Data Quality System

ATTACHMENTS

The following attachments are referenced in Part I of the Region I, EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses. Guidance in some of the documents is superseded by the more recent guidance provided in Part I.

Attachment A		"Quality Assurance for Superfund Environmental Data Collection Activities" - Publication 9200.2-16FS, February 1993, and "EPA Order 5360.1, Draft 1995 Quality Assurance Order".
Attachment B		"Region I Tiered Organic and Inorganic Data Validation Guidelines", July 1, 1993, DRAFT.
Attachment C		"Region I CSF Completeness Evidence Audit Program", July 1991.
Attachment D		"Specifications and Guidance for Contaminant-Free Sample Containers" - Publication 9240.0-05A, EPA/540/R-93/051, December 1992.
Attachment E		"User's Guide to the Contract Laboratory Program", EPA/540/P-91/002, January 1991.
Attachment F		Region I Short Sheets and EPA CLP Information Sheets.
Attachment G		"Training Manual for Reviewing Laboratory Data Package Completeness", June 1994.
Attachment H		"EPA Region I Performance Evaluation Program Guidance", July 1996, Revision.
Attachment I		"Standard Operating Procedures for Submitting Data for Reduced Payment/Data Rejection", September 9, 1991.
Attachment J		Data Validation Report - Blank Forms
	i.	DQO Summary Form
	ii.	ORDA/IRDA Form
	iii.	Telephone Log or Regional/Laboratory Communication Form
	iv.	Data Validation Worksheets
	v.	Chain-of-Custody Form
	vi.	Traffic Report
Attachment K		Example of Contract Compliance Screening (CCS) Report
Attachment L		"Guidance Document for Completing Region I Data Validation Utilizing CADRE Data Review", February 1995.
Attachment M		Example Tier I Validation Cover Letter
Attachment N		Example Tier III Data Validation Reports
Attachment O		"March 7, 1995 Memorandum to Heidi Horahan, ARCS DPO re: CLP-SOW OLM03.1-New Contract Requirements."
Attachment P		"The Regional Sample Control Center Guidance for the Contract Laboratory Program (CLP) and Delivery of Analytical Services (DAS) Program for EPA-New England", November 1996.
Attachment Q		"Region I ARCS Delivery of Analytical Services Pilot Program, Final Report Volume II. Appendices", 15 March 1994.